Docket No.: MIY-P03-006
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gellman et al.

Application No.: 10/774826 Confirmation No.: 9242

Filed: February 9, 2004 Art Unit: N/A

For: DEVICES FOR MINIMALLY INVASIVE PELVIC SURGERY Examiner: Not Yet Assigned

PETITION TO MAKE SPECIAL
UNDER 37 CFR 1.102(d)

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Submitted herewith is a Petition to Make Special the above-identified patent application.

Attorneys for Applicants hereby state that a preexamination search was conducted. Copies of known references related to the subject matter have been submitted to the PTO attached to Information Disclosure Statement filed on September 10, 2004, and a Preliminary Amendment has also been submitted to the PTO on September 10, 2004, copies of both filings are attached hereto for convenience.

The following art is known to Attorneys for Applicants and may be related to subject matter of the pending claims as presented in the Preliminary Amendment filed on September 10, 2004 for the present application: U.S. Patent No. 4,798,193; U.S. Patent No. 4,824,435; U.S. Patent No. 4,896,668; U.S. Patent No. 5,064,435; U.S. Patent No. 5,112,344; U.S. Patent No. 5,152,749; U.S. Patent No. 5,234,457; U.S. Patent No. 5,334,185; U.S. Patent No. 5,337,736; U.S. Patent No. 5,354,292; U.S. Patent No. 5,611,515; Norris et al., Journal of Endourology,

Volume 10, page 227-230, June 1996; and Petros and Ulmsten, Scandanavian Journal of Urology and Nephrology Supplement 153, 1993, which are summarized below.

Additionally, we did the following searches:

1. We studied the file history of U.S. Patent No. 6,491,703 and identified two U.S. patents cited therein—U.S. Patent No. 5,250,033 and U.S. Patent No. 5,368,595—that may be related to the subject matter of the pending claims as presented in the Preliminary Amendment filed on September 10, 2004 for the present application. We also electronically searched via the Delphion Web site the hyper links to the references cited in and the references citing these two U.S. patents and identified the following related art: U.S. Patent No. 3,472,232; U.S. Patent No. 3,763,860; U.S. Patent No. 4,983,168; U.S. Patent No.5,167,634; U.S. Patent No. 5,409,469; U.S. Patent No. 5,647,857; U.S. Patent No. 5,935,122; and DE 43 34 419 A1, which are summarized below.

2. We also conducted full-text keyword searches in all of Delphion's databases (i.e., U.S. patents, U.S. patent applications, European patents, European patent applications, WIPO/PCT international patent applications, German databases including granted patents and pending applications, Japanese abstracts, and INPADOC).

1) We used the following search terms: ((mesh or sling or tape) and (pouch or envelope or sleeve or sheath) and urinary). We reviewed the 189 results from this search and identified 10 additional relevant references: U.S. Patent No. 5,417,226; U.S. Patent No. 5,562,717; EP 0417189 B1; EP 0506920 B1; EP 0628288 B1; EP 0831751 B1; EP 1321111 A2; WO96/01597; WO 96/34587; and WO 96/39227, which are summarized below.

2) We also used the following search terms: ((mesh or sling or tape) and (pouch or envelope or sleeve or sheath) and (medical or surgical)) and did not find any additional relevant references.

3) We also used the following search terms: ((mesh or sling or tape) within five words of (pouch or sleeve or sheath)) and limited to U.S. classes 128/600/601

/602/604/606/607/623 or limited to IPC: A61. We did not identify any additional relevant references.

With respect to the subject matter of the references, Applicants submit the following:

1. U.S. Patent No. 3,472,232 – This reference generally relates to a catheter insertion device. In particular, as illustrated in Figure 1 and Figure 7, the catheter 14 is received within the cannular 12. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

2. U.S. Patent No. 3,763,860 – This reference generally relates to a laparoscopy instrument and a method for suturing and ligation. In particular, as noted in Figure 2, a sheath 14 covers a stem 11 and the stem 11 is to be removed from the body while the sheath 14 is left within. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

3. U.S. Patent No. 4,798,193 – This reference generally relates to a protective sheath instrument carrier. In particular, as shown in Figure 7, the instrument is introduced into the sheath through the handle 12. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

4. U.S. Patent No. 4,824,435 – This reference generally relates to an instrument guidance system. As shown in particular in Figures 1 and 3, the instrument comprises a primary guide wire 14 and a secondary guide wire 12. As shown in Figure 2, the primary guide wire 14 is inserted into the lumen of the tube 16. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

5. U.S. Patent No. 4,896,668 – This reference generally relates to a plate set for osteofixation equipped to suture strands. The plate set is for securing a patient's rib cage following surgery and for protecting internal organs during subsequent surgical procedures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

6. U.S. Patent No. 4,983,168 – This reference generally relates to a medical-layered peel-away sheath and the methods of using the sheath. In particular, as shown in Figure 1, a catheter tube 16 is inserted into the target body site through the hollow interior of the peel-away sheath 10. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

7. U.S. Patent No. 5,064,435 – This reference generally relates to self-expanding prosthesis having stable axial length. In particular, as shown in Figure 1, stent 16 is in a relaxed condition. As shown in Figures 2 and 3, the stent is elastically deformed and maintained in a radially reduced configuration by a pliable sheath 38 surrounding the stent 16. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

8. U.S. Patent No. 5,112,344 – This reference generally relates to methods and the surgical instruments for treating female incontinence comprising looping a filamentary element 19 between the wall of the vagina 16 and rectus abdomenis sheath in the interior wall of the abdomen, whereby it passes to each side of the urethra 20 into the correct spatial relationship to the pubis 17. The surgical instrument comprises a tubular shaft 11 having a handle 12 at one end and carried toward its other end a flexible needle element 13 slidably receivable in the shaft 11 and adapted at one end to receive a filamentary element 19 and having an enlarged profiled portion 15 at its other end, whereby when the needle element 13 is received in the shaft 11, the other end of the needle element 13 defines a convergent surface of the other end of the shaft 11 and the one end of the needle element 13 is exposed at one end of the shaft 11. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

9. U.S. Patent No. 5,152,749 – This reference generally relates to a surgical apparatus for the placement of an instrument within a body cavity which comprises a placement device including an elongated element with an exposable tissue piercing tip, a first coupler adjacent to the tip and a structure for selectively exposing the tip and an elongated instrument for placement including a second coupler adapted to be coupled to the first coupler to effect an end-to-end coupling of the device and the instrument whereby the instrument is positioned within the body cavity. This reference also discloses a method for placement of a supra pubic instrument. This

reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

10. U.S. Patent No. 5,167,634 – This reference generally relates to a peelable sheath with hub connector. The peelable sheath includes a sheath formed of a flexible tube having a pair of separation lines arranged longitudinally on radially opposite sides of the tube to form a pair of peelable sheath portions and a hub connector bonded to the proximal end of the sheath. In particular, as shown in Figure 1, the peelable sheath 10 generally comprises a sheath 12, a pair of wings 14 and a hub connector 16. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

11. U.S. Patent No. 5,234,457 – This reference generally relates to a stent assembly, delivery system and the method of manufacture therefor. In particular, Figure 1 shows the stent 10 and Figure 2 shows the stent 10 being compacted into a stent assembly 20. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

12. U.S. Patent No. 5,250,033 – This reference generally relates to a peel-away introducer sheath having proximal fitting. The peel-away introducer sheath includes a tube sheath having a splittable handle at its proximal end. In particular, as shown in Figure 2, the introducer sheath 10 comprises a sheath tube probe and a handle 18 including a first tab 36 and a second tab 38. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

13. U.S. Patent No. 5,334,185 – This reference generally relates to a surgical apparatus for the placement of an instrument within a body cavity. As disclosed in this reference, the instrument preferably is a suprapubic instrument for placement within a bladder. In particular, Figure 1 shows a suprapubic instrument placement device 10 includes a handle 12 with the central slot 14 therein. The instrument further comprises a rigid needle 20. Figures 11A to 11C show the placement of the stent 100 for coupling of the kidney 112 and the bladder 122. The placement system comprises a guide wire 102 and a cystoscope 124. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

14. U.S. Patent No. 5,337,736 – This reference generally relates to a retraction method and apparatus therefor. The method and apparatus are used for in laparoscopic surgery in the body cavity for moving an internal organ or vessel which interferes with the surgery and then maintaining it there apart from a laparoscopic port. In particular, Figure 1 shows a sling 10 of the invention comprising a web or a membrane 12 with one or more lines or leads 14, 16 attached one on each end of the sling 10. Further, the forceps 128 is shown in Figure 8 and Figure 9 to grip one of the leads 130, 132 of a sling 134. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

15. U.S. Patent No. 5,354,292 – This reference generally relates to a surgical device including a specially adapted surgical mesh and a mechanical means for attaching the surgical mesh to the pubic bone. The surgical mesh is mechanically attached to the pubic bone by an orthopedic scope and the peripheral margins of the mesh are either sutured or stapled to the appropriate anatomical structures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

16. U.S. Patent No. 5,368,595 – This reference generally relates to an implant assist apparatus. In particular, Figure 1A shows a braided tubular ligament prosthesis 21 and a substantially leaner cannular 23 enclosing a portion of the prosthesis 21. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

17. U.S. Patent No. 5,409,469 – This reference generally relates to an introducer system having kink-resistant splittable sheaths. As shown in Figure 16, the kink-resistant section 70 has a series of pleats 72. The pleats 72 permit kink-resistant sections 70 to bend more readily within a body 10 without the formation of kinks as shown in Figure 17. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

18. U.S. Patent No. 5,417,226 – This reference generally relates to a female anti-incontinence device including two flexible disks attached to a flexible stem. The device is inserted into the urethra so that the larger disk occludes the bladder neck during sudden tensing of the abdominal muscles, while the smaller disk remains outside the urethra and prevents migration of the device into the bladder. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

19. U.S. Patent No. 5,562,717 – This reference generally relates to electrical stimulation for the treatment of neuromuscular disorders, in particular incontinence. As shown in Figure 27, the insertable electrode comprises an inner core formed by material such as a form or paper/cotton fiber 100 and an outer conductive sheath 101 of knitted or woven conductive fiber. For example, stainless steel fiber or metalized plastic fiber. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

20. U.S. Patent No. 5,611,515 – This reference generally relates to the surgical treatment of a stress urinary incontinence. Figure 5 shows a cross-sectional view of a suture passer. This reference also teaches a surgical drill guide for drilling a hole in the pubic bone for anchoring sutures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

21. U.S. Patent No. 5,647,857 – This reference generally relates to a sheath holding a device against a balloon catheter for delivery in the lumen of a patient. The device can be a stent or graft combination. As shown in Figure 1, the graft delivery system includes a multi-lumen catheter 60 and a sheath 10 holding the stent and graft combination 56 tightly onto the catheter 60. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

22. U.S. Patent No. 5,935,122 – The reference generally relates to a sheath assembly for use in introducing a catheter or other medical instrument into a vessel in the body of a patient. The sheath assembly includes an outer tubular member and an inner tubular member with a conically shaped cap at its distal end. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

23. DE 43 34 419 A1 – This reference generally relates to a surgical aid 1 as shown in Figure 1. The surgical aid 1 has a shaft part 6 with a handle 7 and, at the distal end area of the shaft part, a holding device 8 for at least one surgical instrument 2. A protective covering is also provided which is formed by a sleeve 9 and which is in the covering position covers the pointed end or sharp ends of the surgical instruments 2. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

24. EP 0 417 189 B1 – This reference relates to the field of catheters. In particular, the reference relates to catheters which are adapted to be inserted into the urethral lumen to alleviate obstructive prostatism, a condition quite common in males over the age of 50. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

25. EP 0 506 920 B1 – This reference generally relates to urinary control. In particular, as shown in Figure1, the urinary control includes a urine tube 12 in which a valve 14 is connected. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

26. EP 0 628 288 B1 – This reference teaches a device that provides a precise controlled positioning of a treatment stylet in a tissue targeted for treatment destruction or sampling from a catheter positioned in the vicinity of the target tissue. The term "stylet" is defined to include both solid and hollow probes which are adapted to be passed from a catheter port through normal tissue to target tissues. In particular, Figure 7 shows an electrode 32 at least partially covered by a sleeve 30. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

27. EP 0 831 751 B1 – This reference generally relates to a urethral cap for alleviating urinary incontinence. This reference teaches that the urethral cap can be packaged in a surrounding clear plastic container or envelope to maintain the cleanliness of the cap prior to usage. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

28. EP 1 321 111 A2 – This reference generally relates to a self-cleansing bladder drainage device. The reference teaches that it may prove efficacious to coat the drain member with hydrogel to render it more soft and lubricious to aid in insertion into the urethra. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

29. WO 96/01597 – This reference generally relates to a vessel occlusive apparatus for reversibly occluding a fluid combing vessel in a human or animal. As shown in Figure 5A and 5B, the cable member 58 and the sheath 63 are attached proximate at distal end to a pubic bone

structure 109 in the body on one side of the urethra 64. The sheath 63 is connect to the conduit 60 proximate to a proximal end. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

30. WO 96/34587 – As shown in the representative figure, this reference teaches a urethral plug 1 comprising a cooperating shaft 12 and a balloon 18. Figure 7 shows a package containing a sterile urethral plug 1. The partially opened package 52 contains the exposed plug 1 and the package 52 can serve as a protective sheath, thereby preventing human contact with the sterile plug 1 while attaching the applicator 40. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

31. WO 96/39227 – This reference generally relates to an intra-urethral catheter shaft 32 comprising a plurality of lumens extending between the first end and the second end of the shaft 32. In particular, as shown in Figure 3, a multi-lumen shaft 32 includes several lumens and a protective sheath 71 covering outer surface 52 of the catheter shaft 32. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

32. Norris et al., Journal of Endourology, Volume 10, page 227-230, June 1996 – This reference is entitled "Use of Synthetic Material in Sling Surgery; A Minimally Invasive Approach." This reference teaches affixing a rectangular patch as a sling to allow suspension of the bladder neck by securing sutures to the mobilized edge of the periurethral fascia and the pubourethral ligament with a running stitch. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

33. Petros and Ulmsten, Scandanavian Journal of Urology and Nephrology Supplement 153; 1993 – This reference is entitled "Integral Theory and Its Method for the Diagnosis and Management of Female Urinary Incontinence." This reference teaches, in Part IV, surgical applications of the theory on female urinary incontinence. The surgical applications disclosed are pre-1993 intravaginal slingplasty procedures and the free graft procedures. This reference does not appear to teach a shaft having a curved portion in combination with a sling assembly.

Accordingly, Applicants request that this Petition to Make Special be granted and the application undergo accelerated examination.

Please charge our Deposit Account No. 18-1945 in the amount of $130.00 covering the fee set forth in 37 CFR 1.17(h). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P03-006. A duplicate copy of this paper is enclosed.

Dated: September 10, 2004

Respectfully submitted,

By _____

Agnes S. Lee
Registration No.: 46,862
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicants

PTO/SB/17 (10-03)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 130.00

Complete if Known	
Application Number	10/774826
Filing Date	February 9, 2004
First Named Inventor	Barry N. Gellman
Examiner Name	Not Yet Assigned
Art Unit	N/A
Attorney Docket No.	MIY-P03-006

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 18-1945

Deposit Account Name: Ropes & Gray LLP

The Director is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below	=	Fee Paid
Total Claims		-** =		x		=	
Independent Claims		-** =		x		=	
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 0.00

***or number previously paid, if greater; For Reissues, see above*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	130.00
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify)					

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($) 130.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Agnes S. Lee	*Registration No. (Attorney/Agent)*	46,862	*Telephone*	(617) 951-7794
Signature				*Date*	September 10, 2004

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 9-10-04 Signature: Maura A. Gallagher (Maura A. Gallagher)

Via: First Class Mail	**Atty Dkt No.:** MIY-P03-006
Inventor: Gellman et al.	
Application No.: 10/774826	**Filing Date:** February 9, 2004
Title: DEVICES FOR MINIMALLY INVASIVE PELVIC SURGERY	

Documents Filed:

Preliminary Amendment (6 pages)

Information Disclosure Statement (2 pages)

Form PTO/SB/08a/b (2 pages)

References (AA – AV; BA – BI; CA – CB)

This return postcard

Sender's Initials: ASL/gb	**Date:** September 10, 2004

9535347_1

Docket No.: MIY-P03-006
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gellman et al.

Confirmation No. 9242

Application No.: 10/774826

Art Unit: 3739

Filed: February 9, 2004

Examiner: Not Yet Assigned

For: DEVICES FOR MINIMALLY INVASIVE PELVIC SURGERY

SECOND PRELIMINARY AMENDMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

Prior to examination on the merits, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-162. (Cancelled).

163. (New) A system for treating urinary incontinence comprising,

a shaft having a curved portion; and

a sling assembly including a sling and a pouch enclosing at least partially the sling, and having an end for associating with an end of the shaft.

164. (New) The system of claim 163, wherein the shaft comprises first and second ends, the first end of the shaft attaches to a handle, and the second end of the shaft associates with the sling assembly.

165. (New) The system of claim 163, wherein the shaft comprises a channel located at a distal end.

166. (New) The system of claim 165, wherein the channel is lockable for locking the end of the sling assembly in the channel.

167. (New) The system of claim 166, wherein the channel is releasably lockable.

168. (New) The system of claim 163 comprising a spring loaded locking mechanism for locking the end of the sling assembly in the channel.

169. (New) The system of claim 163, wherein the sling assembly comprises a sling.

170. (New) The system of claim 163, wherein the sling assembly comprises an elongated extension located at the end of the sling assembly.

171. (New) The system of claim 163, wherein the sling assembly comprises an aperture located at the end of the sling assembly.

172. (New) The system of claim 163, wherein the sling assembly comprises a sling and a pouch enclosing at least partially the sling.

173. (New) The system of claim 172, wherein the pouch comprises an opening intermediate to first and second ends of the sling assembly.

174. (New) The system of claim 172, wherein the pouch is substantially flat.

175. (New) A system for treating urinary incontinence comprising,

a shaft having a curved portion and an interlocking mating structure on a distal end of the shaft; and

a sling assembly having a complementary interlocking mating structure.

176. (New) The system of claim 175, wherein the interlocking mating structure of the shaft is inserted into the complementary interlocking mating structure of the sling assembly.

177. (New) The system of claim 175, wherein the shaft is lockable to the sling assembly.

178. (New) The system of claim 175, wherein the shaft is releasably lockable to the sling assembly.

179. (New) The system of claim 175, wherein the sling assembly is indirectly connected to the shaft.

180. (New) The system of claim 175, wherein the complementary interlocking mating structure is indirectly connected to the sling assembly.

181. (New) The system of claim 175, wherein the sling assembly comprises a sling.

182. (New) The system of claim 175, wherein the sling assembly comprises a sling and a pouch enclosing at least partially the sling.

183. (New) The system of claim 182, wherein the pouch comprises an opening intermediate to first and second end of the sling assembly.

184. (New) The system of claim 182, wherein the pouch is substantially flat.

185. (New) A system for treating urinary incontinence comprising,

a shaft having a curved portion and a distal end; and

a sling assembly having an end for receiving the distal end of the shaft.

186. (New) The system of claim 185, wherein the shaft is lockable to the sling assembly.

187. (New) The system of claim 185, wherein the shaft is releasably lockable to the sling assembly.

188. (New) The system of claim 185, wherein the sling assembly is indirectly connected to the shaft.

189. (New) The system of claim 185, wherein the sling assembly comprises a sling.

190. (New) The system of claim 185, wherein the sling assembly comprises a sling and a pouch enclosing at least partially the sling.

191. (New) The system of claim 190, wherein the pouch comprises an opening intermediate to first and second ends of the sling assembly.

192. (New) The system of claim 190, wherein the pouch is substantially flat.

193. (New) A system for treating urinary incontinence comprising,

a handle;

a shaft attached to the handle and having a channel located at an end and a curved portion; and

a sling assembly having an end for associating with the channel of the shaft.

194. (New) The system of claim 193, wherein the channel is lockable for locking the end of the sling assembly in the channel.

195. (New) The system of claim 193, wherein the channel is releasably lockable.

196. (New) The system of claim 193 comprising a spring loaded locking mechanism for locking the end of the sling assembly in the channel.

197. (New) The system of claim 193, wherein the sling assembly comprises an elongated extension located at the end of the sling assembly.

198. (New) The system of claim 193, wherein the sling assembly comprises an aperture located at the end of the sling assembly.

199. (New) The system of claim 193, wherein the sling assembly comprises a sling.

200. (New) The system of claim 193, wherein the sling assembly comprises a sling and a pouch enclosing at least partially the sling.

201. (New) The system of claim 200, wherein the pouch comprises an opening intermediate to first and second ends of the sling assembly.

202. (New) The system of claim 202, wherein the pouch is substantially flat.

REMARKS

Applicants hereby cancel claims 1-162 without prejudice.

Applicants hereby add new claims 163-202. Support for new claims 163-202 can be found throughout the specification of the present application, for example, at pages 23-38 and 55-63. Accordingly, no new matter is added by the introduction of new claims 163-202.

In view of the above amendment, Applicants request approval and entry of these amendments and allowance of claims 163-202 in due course.

Applicants believes no fee is due with this preliminary amendment. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. MIY-P03-006 from which the undersigned is authorized to draw.

Dated: September 10, 2004

Respectfully submitted,

By _____

Agnes S. Lee
Registration No.: 46,862
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant

Docket No.: MIY-P03-006
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Gellman et al.

Application No.: 10/774826 Confirmation No.: 9242

Filed: February 9, 2004 Art Unit: N/A

For: DEVICES FOR MINIMALLY INVASIVE PELVIC SURGERY Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A summary/abstract translation of the non-English language references is enclosed.

A copy of each reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent,

publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. MIY-P03-006.

Dated: September 10, 2004

Respectfully submitted,

By _____

Agnes S. Lee
Registration No.: 46,862
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110-2624
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete If Known	
Application Number	10/774826
Filing Date	February 9, 2004
First Named Inventor	Barry N. Gellman
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	MIY-P03-006

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	3,472,232	10-14-1969		
	AB	3,763,860	10-09-1973		
	AC	4,798,193	01-17-1989		
	AD	4,824,435	04-25-1989		
	AE	4,896,668	01-30-1990		
	AF	4,983,168	01-08-1991		
	AG	5,064,435	11-12-1991		
	AH	5,112,344	05-12-1992		
	AI	5,152,749	10-06-1992		
	AJ	5,167,634	12-01-1992		
	AK	5,234,457	08-10-1993		
	AL	5,250,033	10-05-1993		
	AM	5,334,185	08-02-1994		
	AN	5,337,736	08-16-1994		
	AO	5,354,292	10-11-1994		
	AP	5,368,595	11-29-1994		
	AQ	5,409,469	04-25-1995		
	AR	5,417,226	05-23-1995		
	AS	5,562,717	10-08-1996		
	AT	5,611,515	03-18-1997		
	AU	5,647,857	07-15-1997		
	AV	5,935,122	08-10-1999		

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	BA	DE 4334419	04-13-1995			√
	BB	EP 0417189	12-14-1989			
	BC	EP 0506920	04-30-1992			
	BD	EP 0628288	12-14-1994			
	BE	EP 0831751	12-19-1996			
	BF	EP 1321111	06-25-2003			
	BG	WO96/01597	01-25-1996			
	BH	WO96/34587	11-07-1996			
	BI	WO96/39227	12-12-1996			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
Examiner Signature		Date Considered	

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete If Known	
Application Number	10/774826
Filing Date	February 9, 2004
First Named Inventor	Barry N. Gellman
Art Unit	3739
Examiner Name	Not Yet Assigned
Attorney Docket Number	MIY-P03-006

	CA	Papa Petros, P.E. and Ulmsten, Ulf I., "An Integral Theory and its Method For the Diagnosis and Management of Female Urinary Incontinence", Scandinavian Journal of Urology and Nephrology Supplement No. 153, pp. 1 - 93 (1993)	
	CB	Norris et al., "Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach", Journal of Endourology, Vol. 10, No. 3, pp. 227 - 230 (1996)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	

PTO/SB/92 (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application No. (if known): 10/774826 Attorney Docket No.: MIY-P03-006

Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On 9-10-04 .
Date

Maura A. Gallagher
Signature

Maura A. Gallagher
Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

IDS (Citation) by Applicant (2 pages)
Information Disclosure Statement (2 pages)
References (AA – AV; BA – BI; CA – CB)

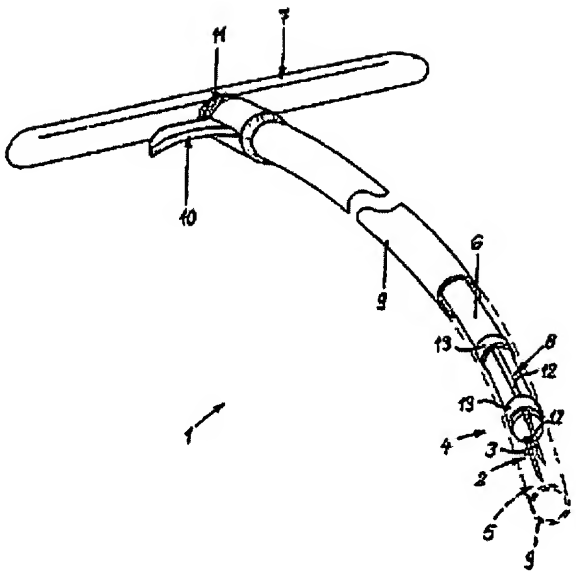
BA

Surgical aid

Patent number:	DE4334419
Publication date:	1995-04-13
Inventor:	HACKLAENDER ANDREAS DR MED (DE)
Applicant:	UNIV LUDWIGS ALBERT (DE)
Classification:	
- international:	A61B17/00
- european:	A61B17/00E, A61B17/04E
Application number:	DE19934334419 19931008
Priority number(s):	DE19934334419 19931008

Abstract of **DE4334419**

A surgical aid (1) is used for introducing pointed and/or sharp surgical instruments (2) into the body of a patient and for positioning these instruments at an operating site.
It has a shaft part (6) with handle (7) and, at the distal end area of the shaft part, a holding device (8) for at least one surgical instrument (2). A protective covering is also provided which is formed by a sleeve (9) and which in the covering position covers the pointed and/or sharp ends of the surgical instruments (2). In the working position, this protective covering can be removed from the handle area.



(19) BUNDESREPUBLIK DEUTSCHLAND

DEUTSCHES PATENTAMT

(12) **Offenlegungsschrift**

(10) **DE 43 34 419 A 1**

(51) Int. Cl.[6]: A 61 B 17/00

(21) Aktenzeichen: P 43 34 419.4
(22) Anmeldetag: 8. 10. 93
(43) Offenlegungstag: 13. 4. 95

DE 43 34 419 A 1

(71) Anmelder:
Klinikum der Albert-Ludwigs-Universität Freiburg, 79106 Freiburg, DE

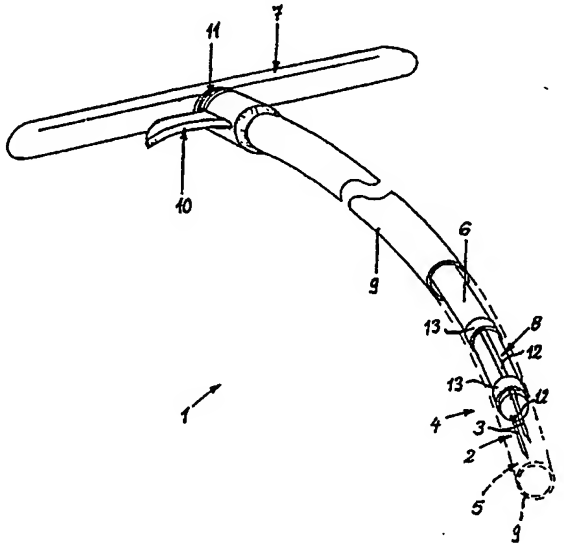
(74) Vertreter:
Schmitt, H., Dipl.-Ing.; Maucher, W., Dipl.-Ing., Pat.-Anwälte, 79102 Freiburg

(72) Erfinder:
Hackländer, Andreas, Dr.med., 79104 Freiburg, DE

Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Operationshilfsinstrument

(57) Ein Operations-Hilfsinstrument (1) dient zum Einbringen von spitzen und/oder scharfen Operations-Werkzeugen (2) in den Körper eines Patienten und zum Positionieren dieser Werkzeuge an einer Operationsstelle.
Es weist ein Schaftteil (6) mit Griff (7) und am distalen Endbereich des Schaftteiles eine Halterung (8) für wenigstens ein Operations-Werkzeug (2) auf. Weiterhin ist eine durch eine Hülse (9) gebildete Schutzabdeckung vorgesehen, die in Abdeckstellung die spitzen und/oder scharfen Enden der OP-Werkzeuge (2) abdeckt. In Arbeitsstellung ist diese Schutzabdeckung vom Griffbereich her entfernbar.



DE 43 34 419 A 1

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

BUNDESDRUCKEREI 02. 95 508 015/231

Beschreibung

Die Erfindung bezieht sich auf ein Operationshilfsinstrument zum Einbringen von spitzen und/oder scharfen Operationswerkzeugen in den Körper eines Patienten und zum Positionieren dieser Werkzeuge an einer Operationsstelle, mit einem Griffteil sowie einem Schaftteil, insbesondere zum Anschlingen und Transportieren von Organen, Organteilen und dergleichen Körperteilen.

Bei endoskopischen und/oder herkömmlichen chirurgischen Eingriffen ist es mitunter unentbehrlich, spitze oder scharfe Werkzeuge in den zu operierenden Bereich einzubringen, ohne das um liegende, nicht zu operierende Gewebe zu verletzen. Beispielsweise sei die Orchidopexie genannt, bei der es erforderlich ist, eine bzw. zwei Nadeln mit Faden entlang dem Leistenkanal über eine bestimmte Strecke ohne Sicht in den Hodensack einzubringen, denselben zu durchstechen, um dann den heruntergezogenen Hoden zu pexieren.

Aufgabe der vorliegenden Erfindung ist es, ein Operationshilfsinstrument zu schaffen, mit dem spitze bzw. scharfe Operationswerkzeuge gefahrlos auch unter beengten Verhältnissen an den jeweiligen Einsatzort gebracht werden können.

Zur Lösung dieser Aufgabe wird erfindungsgemäß insbesondere vorgeschlagen, daß am distalen Endbereich des Schaftteiles des Instrumentes eine Halterung für wenigstens ein Operations-Werkzeug vorgesehen ist und daß das Operationswerkzeug im Bereich seines spitzen und/oder scharfen Endes eine in Arbeitsstellung entfernbare Schutzabdeckung aufweist.

Die Schutzabdeckung befindet sich beim Einführen und Positionieren des Instrumentes über den Arbeitsenden des oder der Werkzeuge. Die Werkzeuge können so auch entlang von engen, zum Beispiel schlauchförmigen Körperhöhlungen geführt werden ohne daß dabei die Gefahr des Einhakens und damit eine Verletzungsgefahr besteht. Am Operationsort beziehungsweise jeweils dort, wo die gehaltenen Werkzeuge aktiviert werden, kann die Schutzabdeckung so weit entfernt werden, daß die Werkzeuge dann einsetzbar bzw. handhabbar sind.

Bevorzugt ist das Operationshilfsinstrument für die Pexie einsetzbar, wo ein Körperteil oder dergleichen mit einem Faden angeschlungen und dann transportiert und gegebenenfalls festgelegt wird.

Zweckmäßigerweise ist die Schutzabdeckung durch eine auf dem Schaftteil verschiebbare Hülse gebildet. Eine solche Schutzabdeckung läßt sich einfach realisieren und bietet praktisch einen "Rundumschutz" mit besonders hoher Sicherheit gegen Berührung der geschützten Werkzeuge.

Eine bevorzugte Ausführungsform der Erfindung sieht vor, daß als Operations-Werkzeuge wenigstens eine, vorzugsweise zwei Nadeln vorgesehen sind, die in Transportstellung in seitlichen, axial orientierten Aufnahmenuten des Schaftteiles eingesetzt und gehalten sind und mit ihren Nadelspitzen über das distale Schaftende überstehen und daß die Schutzabdeckungs-Hülse bis über die Nadelspitzen verschiebbar ist.

Dieses Operationshilfsinstrument kann insbesondere auch gut für die Orchidopexie eingesetzt werden, da hierbei die am hochstehenden Hoden angeschlungenen Fäden mit den Nadeln von der Leiste her in den Hodensack hinein und mit Hilfe der Nadeln nach außen gebracht werden können, so daß kein Operationsschnitt im Hodensackbereich erforderlich ist.

Somit ist unter anderem der Operationsvorgang insgesamt wesentlich vereinfacht.

Zweckmäßigerweise ist die Schutzabdeckungs-Hülse mittels eines beim Griffteil befindlichen Fingergriffes oder dergleichen betätigbar. Dadurch ist eine Betätigung der durch den distalen Endbereich der Hülse gebildeten Schutzabdeckung von außen her auch ohne direkte Sicht oder direkten Zugriff des Werkzeuges möglich. Die Übertragung vom Fingergriff zur Schutzabdeckung erfolgt über die zum Fingergriff hin verlängerte Hülse.

Zusätzliche Ausgestaltungen der Erfindung sind in den weiteren Unteransprüchen aufgeführt. Nachstehend ist die Erfindung mit ihren wesentlichen Einzelheiten anhand der Zeichnungen noch näher erläutert.

Es zeigt

Fig. 1 eine perspektivische Ansicht eines Operations-Hilfsinstrumentes, zum Teil im Schnitt dargestellt und

Fig. 2 bis 4 die wesentlichen Einzelteile des in Fig. 1 gezeigten Instrumentes mit Schaftteil (Fig. 2), Hülsenteil (Fig. 3) und Druckfeder (Fig. 4).

Ein in Fig. 1 gezeigtes Operations-Hilfsinstrument 1 dient zum Einbringen von spitzen und/oder scharfen Operations-Werkzeugen 2 in den Körper eines Patienten und zum Positionieren dieser Werkzeuge an einer Operationsstelle. Im dargestellten Ausführungsbeispiel sind als Operations-Werkzeuge zwei Nadeln 3 vorgesehen.

Diese Nadeln 3 sind am distalen Ende 4 des Hilfsinstrumentes in eine Halterung eingesetzt. In Transportstellung sind die Nadeln 3 durch eine Schutzabdeckung 5, die in Fig. 1 strichliniert angedeutet ist, abgeschirmt. Diese Schutzabdeckung läßt sich so weit zurückziehen, daß die Nadeln 3 in Manipulierstellung zumindest mit ihren freien Endbereichen freiliegen.

Die wesentlichen Einzelteile des Hilfsinstrumentes 1 sind in den Fig. 2 bis 4 dargestellt. Es sind dies ein Schaftteil 6 (Fig. 2) mit Griff 7 und Werkzeug-Halterung 8, weiterhin eine Schutzabdeckungs-Hülse 9 (Fig. 3) mit einem Fingergriff 10 sowie eine Druckfeder 11 (Fig. 4).

Die Halterung 8 am distalen Ende des Schaftteiles 6 ist im wesentlichen durch zwei etwa diametral gegenüberliegende Aufnahmenuten 12 sowie zwei im Bereich der Aufnahmenuten 12 befindliche Halteringe 13 gebildet.

Bei der Montage der Einzelteile des Hilfsinstrumentes wird zuerst die Druckfeder 11 auf das Schaftteil 6 und anschließend die Schutzabdeckungs-Hülse 9 vom distalen Ende 4 her aufgeschoben. In Funktionsstellung stützt sich dann die Druckfeder 11 einerseits am Griff 7 und andererseits am äußeren Ende der Hülse 9 bzw. dem Fingergriff 10 ab. Durch diese Druckfeder wird die Hülse, bezogen auf die gehaltenen Werkzeuge 2 in Schließstellung gehalten. Durch Betätigen des Fingergriffes 10 kann die Hülse 9 zum Griff 7 hin zurückgezogen werden, so daß dann die Endbereiche der Werkzeuge freigegeben sind.

Zumindest in der Abdeckstellung der Hülse 9 kann sich eine Rasteinrichtung in Eingriff befinden, so daß diese Stellung etwas abgesichert ist, bei Betätigen des Fingergriffes 10 andererseits aber auch leicht überwunden werden kann. Gleiches gilt auch für eine Zwischenstellung bzw. eine Freigabestellung.

Die Nadeln 3 können vom freien Ende des Schaftteiles 6 her in die Aufnahmenuten 12 eingeschoben werden und werden dort durch die Halteringe 13 klemmend gehalten.

Das mit zwei Nadeln 3 als Operations-Werkzeugen

ausgestattete Hilfsinstrument läßt sich besonders gut für die Orchidopexie einsetzen. Die Aufgabe besteht in diesem Falle darin, einen hochstehenden Hoden durch den Leistenkanal in den Hodensack zu transportieren und dort zu fixieren. Bislang war es dazu erforderlich, im Bereich des hochstehenden Hodens den Leistenkanal zu öffnen und den Hoden an einen Faden anzuschlingen. Vom geöffneten Hodensack her wurde dann eine lange Faßzange eingeführt und über den Leistenkanal bis zu dem hochstehenden Hoden geführt. Die Fäden wurden dann gefaßt und der daran angeschlungene Hoden nach unten in den Hodensack gezogen. Es sind somit Operationsschnitte sowohl im Bereich des Hodensacks als auch im Leistenbereich erforderlich und außerdem stellt das Einführen der Faßzange eine recht umständliche Manipulation dar.

Mit dem erfindungsgemäßen Operations-Hilfsinstrument wird nun nur noch im Leistenbereich, dort wo der hochstehende Hoden sitzt, ein Operationsschnitt ausgeführt. Der hochstehende Hoden mit dann mit Hilfe der zwei Nadeln 3 und einem Faden angeschlungen. Die beiden über den Faden verbundenen Nadeln 3 werden dann in die Halterung 8 des Hilfsinstrumentes 1 eingesetzt und durch die Hülse 9 geschützt durch den Leistenkanal bis in den Hodensack transportiert. Dort wird die Hülse 9 so weit zurückgezogen, daß mit Hilfe der beiden Nadeln 3 der Hodensack von innen nach außen durchstochen werden kann. Die beiden Nadeln werden dann von außen gefaßt und über den daranhängenden Faden wird der hochstehende Hoden durch den Leistenkanal in den Hodensack gezogen.

Mit Hilfe des Fadens läßt sich dann der heruntergezogene Hoden im Hodensack fixieren.

Insbesondere für die Orchidopexie ist das Schaftteil 6 in Anpassung an den Verlauf des Leistenkanales passend gebogen, wie dies gut auch in Fig. 2 erkennbar ist. Das Schaftteil 6 kann beispielsweise aus einem etwa 4 mm dickem Rundmaterial bestehen und eine Länge von beispielsweise 18,5 cm aufweisen. Die Krümmung kann bei dieser Länge etwa 50° betragen.

Die Hülse 9 ist in gleichem Maße gebogen wie das Schaftteil 6 und besteht vorzugsweise aus V4a-Rohr. Der Innendurchmesser kann beispielsweise 5 mm und der Außendurchmesser 6 mm betragen.

Insgesamt ist somit das Hilfsinstrument vergleichsweise schlank ausgebildet und kann deshalb problemlos durch den Leistenkanal geführt werden.

Außer zur Orchidopexie läßt sich das Hilfsinstrument in gegebenenfalls etwas abgewandelter Ausführungsform auch für andere Operationen verwenden. Beispielsweise läßt sich ein Organ oder Organteil an einer bestimmten Stelle der Bauchdecke befestigen, indem diese mit Hilfe der Nadeln 3 durchstochen wird und dann außenseitig ein Fixieren des innen angeschlungenen Teiles vorgenommen wird.

Patentansprüche

1. Operations-Hilfsinstrument zum Einbringen von spitzen und/oder scharfen Operations-Werkzeugen in den Körper eines Patienten und zum Positionieren dieser Werkzeuge an einer Operationsstelle, mit einem Griffteil sowie einem Schaftteil, insbesondere zum Anschlingen und Transportieren von Organen, Organteilen und dergleichen Körperteilen, **dadurch gekennzeichnet**, daß am distalen Endbereich (4) des Schaftteiles (6) eine Halterung (8) für wenigstens ein Operations-Werkzeug (2) vorgesehen ist und daß das Operations-Werkzeug im Bereich seines spitzen und/oder scharfen Endes eine in Arbeitsstellung entfernbare Schutzabdekkung (9) aufweist.

2. Hilfsinstrument nach Anspruch 1, dadurch gekennzeichnet, daß die Schutzabdeckung durch eine auf dem Schaftteil (6) verschiebbare Hülse (9) gebildet ist.

3. Hilfsinstrument nach Anspruch 1 oder 2, dadurch gekennzeichnet, daß als Operations-Werkzeuge (2) wenigstens eine, vorzugsweise zwei Nadeln (3) vorgesehen sind, die in Transportstellung in seitlichen, axial orientierten Aufnahmenuten (12) des Schaftteiles (6) eingesetzt und gehalten sind und mit ihren Nadelspitzen über das distale Schaftende (4) überstehen und daß die Schutzabdeckungs-Hülse (9) bis über die Nadelspitzen verschiebbar ist.

4. Hilfsinstrument nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß zum klemmenden Halten der in den Aufnahmenuten (12) befindlichen Nadeln (3) oder dergleichen Werkzeuge wenigstens ein das Schaftteil (6) im Bereich der Aufnahmenuten umgreifender Haltering (13) vorgesehen ist.

5. Hilfsinstrument nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die beiden Nadeln (3) mit den Enden eines gemeinsamen Fadens verbunden sind.

6. Hilfsinstrument nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß die Schutzabdekkungs-Hülse (9) mit einem beim Griffteil (7) befindlichen Fingergriff (10) oder dergleichen betätigbar ist.

7. Hilfsinstrument nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, daß die Schutzabdekkungs-Hülse (9) durch Federkraft in Abdeck- bzw. Schutzlage gehalten ist und gegen diese Federkraft in Freigabeposition verschiebbar ist und daß als Rückstellfeder vorzugsweise eine beim Griffteil zwischen diesem und dem Fingergriff (10) auf dem Schaftteil (6) gelagerte Druckfeder (11) vorgesehen ist.

8. Hilfsinstrument nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß die Länge des Schaftteiles (6) etwa 10 cm bis 20 cm beträgt und daß der Schaftdurchmesser vorzugsweise etwa 4 mm und der Durchmesser der Schutzabdekkungs-Hülse (9) vorzugsweise etwa 6 mm beträgt.

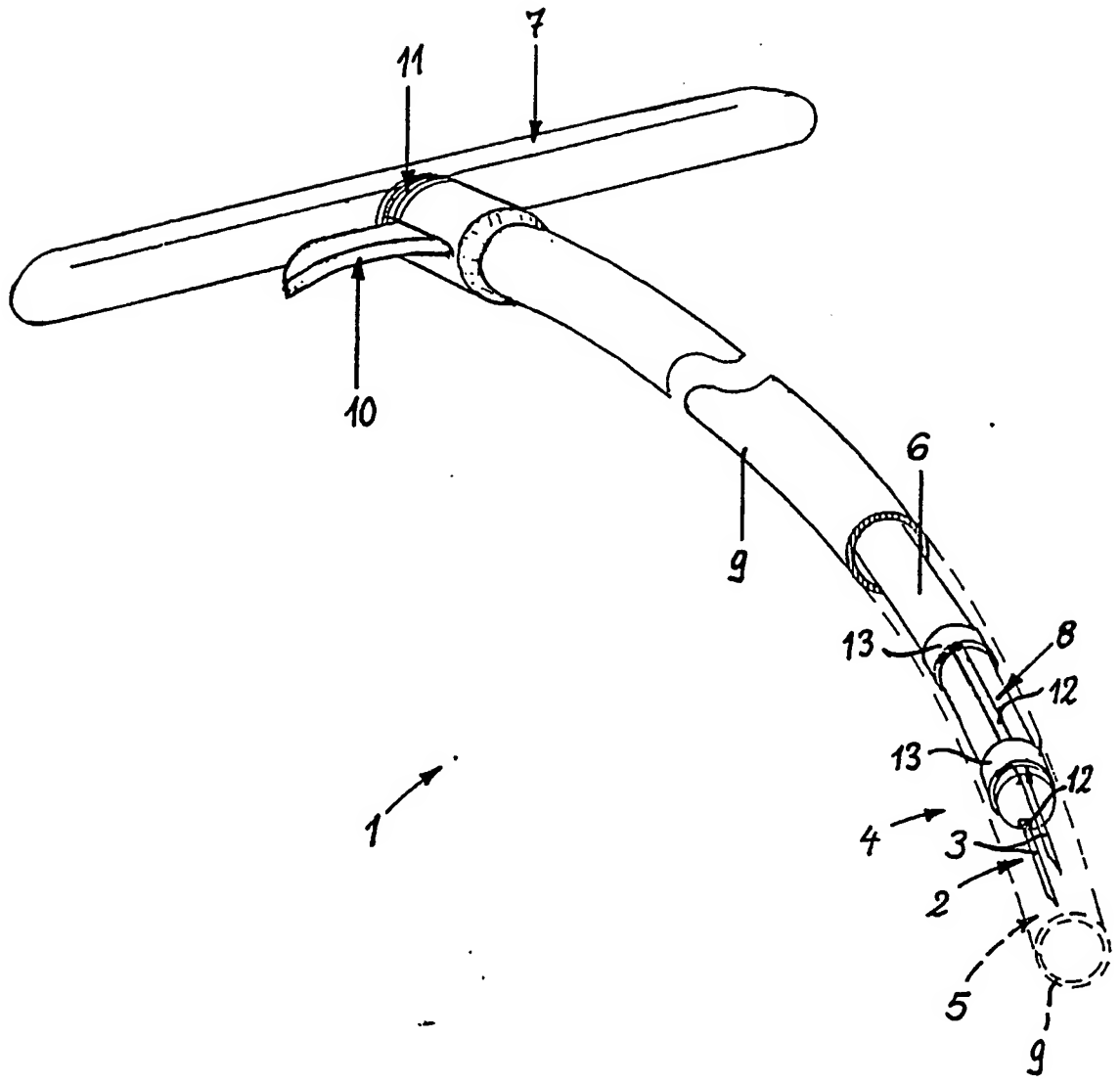
9. Hilfsinstrument nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß der Schaftteil (6) und dergleichen im Verlauf seiner Längserstrekkung gekrümmt ausgebildet ist.

Hierzu 2 Seite(n) Zeichnungen

– Leerseite –

Nummer: DE 43 34 419 A1
Int. Cl.[6]: A 61 B 17/00
Offenlegungstag: 13. April 1995

Fig.1



Nummer: DE 43 34 419 A1
Int. Cl.[6]: A 61 B 17/00
Offenlegungstag: 13. April 1995

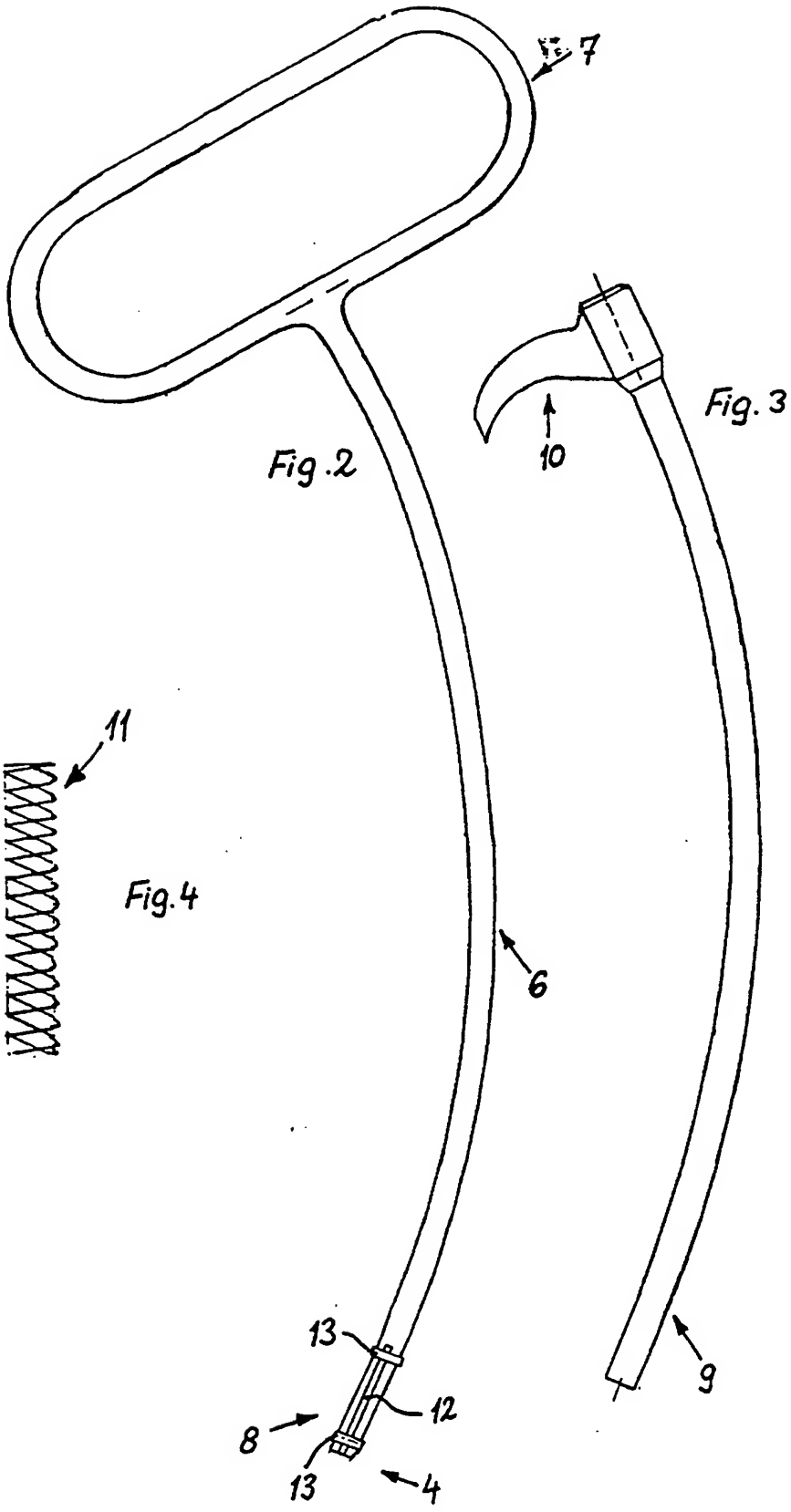


Fig. 2

Fig. 3

Fig. 4

BB

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 417 189 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
15.10.1997 Bulletin 1997/42

(21) Application number: **89906911.6**

(22) Date of filing: **02.06.1989**

(51) Int. Cl.[6]: **A61M 29/02**, A61M 25/10

(86) International application number:
PCT/US89/02423

(87) International publication number:
WO 89/11890 (14.12.1989 Gazette 1989/29)

(54) BALLOON DILATION CATHETER

BALLON-DILATATIONSKATHETER

CATHETER DE DILATATION PAR BALLON

(84) Designated Contracting States:
AT BE CH DE FR GB IT LI LU NL SE

(30) Priority: **02.06.1988 US 201686**
01.06.1989 US 360088

(43) Date of publication of application:
20.03.1991 Bulletin 1991/12

(73) Proprietor: **BOSTON SCIENTIFIC IRELAND LIMITED**
Saint Michael, Barbados, West Indies (BB)

(72) Inventors:
- **ROSENBLUTH, Robert, F.**
  Laguna Niguel, CA 92677 (US)
- **LENKER, Jay, Alan**
  Laguna Beach, CA 92651 (US)
- **GREENE, George, Robert**
  Costa Mesa, CA 92626 (US)
- **CALVARESE, Barry, M.**
  Cardiff, CA 92007 (US)

(74) Representative: **Maury, Richard Philip et al**
Sommerville & Rushton,
45 Grosvenor Road
St. Albans, Herts AL1 3AW (GB)

(56) References cited:

US-A- 3 045 677	US-A- 3 720 199
US-A- 3 822 702	US-A- 3 848 602
US-A- 4 445 892	US-A- 4 461 280
US-A- 4 561 446	US-A- 4 660 560
US-A- 4 697 595	US-A- 4 733 652
US-A- 4 738 659	US-A- 4 762 128

EP 0 417 189 B1

Printed by Rank Xerox (UK) Business Services
2.14.16/3.4

Description

Background of the Invention

The present invention relates generally to the field of catheters. More specifically, the present invention relates to catheters which are adapted to be inserted into the urethral lumen to alleviate obstructive prostatism, a condition quite common in males over the age of 50.

The prostate is a somewhat pear-shaped gland that extends around the urethral lumen from the neck of the bladder to the pelvic floor. Because of the close relationship of the prostate to the urethra, enlargement of the prostate, usually referred to as hypertrophy or hyperplasia, may fairly quickly obstruct the urethra, particularly if the hyperplasia occurs close to the lumen. Such an obstruction inhibits normal micturition, which causes an accumulation of urine in the bladder.

The surgical treatment of hyperplasia of the prostate gland has been a routine procedure in the operating room for many years. One method of surgical treatment is open prostatectomy whereby an incision is made to expose the enlarged prostate gland and remove the hypertrophied tissue under direct vision. Another method of treating obstructive prostatism is a technique known as transurethral resection. In this procedure, an instrument called a resectoscope is placed into the external opening of the urethra and an electrosurgical loop is used to carve away sections of the prostate gland from within the prostatic urethra under endoscopic vision.

The technique of transurethral resection offers many benefits to the patient as compared to open prostatectomy. Using this technique, the trained urologist can remove the hypertrophied prostate with less patient discomfort, a shorter hospital stay and lower rates of mortality and morbidity. Over 333,000 patients underwent this procedure in the United States in 1985, with an average hospital stay of six days. Notwithstanding the significant improvement in patient care resulting from the widespread application of transurethral resection, there remains a need for a less invasive method of treating the symptoms of prostate disease.

One of the earliest methods of relieving acute urinary retention, a symptom associated with prostate disease, was the placement of a catheter through the external urethral opening into the bladder, thereby allowing the outflow of urine from the bladder by way of the catheter lumen. These urinary catheters typically employ a balloon at the tip which, when inflated, prevents the expulsion of the catheter from the body. However, due to problems of infection, interference with sexual activity, and maintenance involved with such catheters, they are generally unacceptable for long term treatment of micturition problems.

U.S. Patent No. 4,432,757 to Davis, Jr. teaches the use of an indwelling urethral catheter assembly, having a Foley-type balloon disposed near the distal end thereof and a substantially non-compliant balloon lead shaft proximate to the Foley-type balloon. The device is adapted to be inserted through the urethra up into the bladder. The Foley-type balloon and the balloon lead shaft are then inflated, although the balloon lead shaft remains relatively non-compliant and therefore does not expand appreciably. Gentle traction is then applied to a catheter sleeve head to sever the sleeve from the remainder of the catheter, leaving the balloon lead shaft in position within the urethra.

Another method of treating hypertrophy of the prostate gland without the need for surgery has been to inject medications into the prostate gland by means of a catheter. Such a device is disclosed in U.S. Patent No. 550,238 to Allen, wherein two balloons are disposed along two sections of a catheter, and inflated to isolate an area within the urethra prior to the injection of the medication. However, these injections are frequently ineffective as the prostate gland exhibits only a limited ability to absorb the injected antibiotics, and proper positioning and retaining of the catheter with respect to the affected area is extremely difficult.

A substantial improvement in an apparatus and corresponding method of treatment for obstructive prostatic hypertrophy is disclosed in Klein, U.S. Patent No. 4,660,560 from which the generic part of claim 1 is derived. In Klein's method, a calibrating catheter is used to measure the distance between the neck of the bladder and the bottom of the prostate gland. A dilation catheter, having an annular balloon with a length equivalent to the measured length, and a Foley-type balloon at the distal end thereof is then inserted into the urethra until the Foley-type balloon is within the bladder. The Foley balloon is then inflated in the bladder and is used to position the dilation balloon in the prostrate. The latter balloon is then inflated, to force the prostate away from the urethral lumen. Use of the Klein catheter can effectively eliminate uncertainty regarding positioning of the upper (distal) end of the dilation balloon, thereby significantly facilitating the treatment of prostatic hypertrophy.

In practicing the Klein method, after the calibration catheter is used to measure the length of the affected prostate, it is withdrawn from the urethra, and the dilation catheter is then inserted. Proper insertion of the dilation catheter is crucial, as stretching of the external urethral sphincter muscle, which lies just below the prostate, could cause incontinence.

Accordingly, in practicing the method of the Klein patent, there is a need for a method and apparatus to permit effective and sure positioning of the proximal end of the dilation balloon with respect to the external urethral sphincter. There is a particular need to permit visualisation of the balloon placement in vivo during the course of the surgical procedure.

Briefly, the present invention provides an intraluminal dilation apparatus according to Claim 1.

Preferably, the dilation catheter is provided with an expandable locating balloon, disposed near the distal tip of the catheter which, when inflated within the bladder,

will provide an anchor with the bladder neck. At least one dilation balloon is preferably provided on the catheter, proximate the locating balloon which, when inflated, conforms to a preselected configuration, so as to radially outwardly dilate the obstruction away from the urethral lumen.

In use, the symptoms of obstructive prostatism are treated by dilation of the prostatic urethra, comprising the steps of inserting the dilation means into the urethra. The location of the dilation means within the urethra is adjusted with respect to an anatomical landmark using non-radiological locating means, i.e. the visible indicator and the dilation means is thereafter expanded so as to radially outwardly dilate the prostatic urethra.

Further objects, features and other advantages of the present invention will become apparent from the ensuing detailed description of preferred embodiments, by way of example only, considered together with the appended drawings.

Figure 1 is a perspective view of a dilation catheter and sheath assembly in accordance with one embodiment of the present invention;
Figure 2 is a partial assembly view of the clipping mechanism;
Figure 3 is a perspective view of a septum, showing an inwardly extending boot sleeve in cut away;
Figure 3a is a perspective view of a second type of septum, having both boot sleeves projecting outwardly;
Figure 4 is an end view of the sheath, showing the unique ellipsoid shape of the inner walls thereof;
Figure 5 is a perspective view of the tip of the sheath, as being deformed by a once-inflated dilation balloon, so as to guide the balloon into the sheath before removal from the urethral lumen;
Figure 6 is a side view of the tip of an obturator;
Figure 7 is a side view of the sheath, having an obturator disposed therein, as ready for insertion into the urethra;
Figure 8 is a cross-sectional view, taken along line 8-8 of Figure 7, showing in more detail the obturator removably disposed therein;
Figure 9 is a cross-sectional view, illustrating a plastic manifold disposed at the proximal end of the dilation catheter during the molding process;
Figure 10 is a cross-sectional view, taken along line 10-10 of Figure 11, showing the lumen arrangement within the catheter shaft;
Figure 11 is a side view of a dilation catheter, having a stylet removably inserted therein;
Figure 12 is a cross-sectional view, taken along line 12-12 of Figure 11, showing the overlap of the shoulder of the locating balloon with the shoulder of the dilation balloon;
Figure 13 is a side view of a dilation balloon, in an inflated state, exhibiting a squared-off configuration at one end, and a tapered configuration at the opposite end thereof, in accordance with one embodiment of the present invention;
Figure 14 is a side view of a dilation balloon, having both ends in a tapered configuration, in accordance with an alternative embodiment of the present invention;
Figure 15 is a side view of a calibration catheter, showing a partial cut away view of an inflation aperture for the expandable balloon;
Figure 16 is a magnified view of the marking disposed near the proximal end of the dilation balloon showing clearance of the external sphincter muscle; and
Figure 17 is a cross-sectional view of the urethral dilation catheter of the present invention operatively inserted within the male urinary tract.
Figure 18 is a perspective view of a dilation catheter having an internal obturator thereon.
Figure 19 is a perspective view of a dilation apparatus having a locking bridge.
Figure 20 is an enlarged perspective view of a locking bridge.

Referring now to the drawings in detail, wherein like reference numerals designate like elements throughout the several views thereof, there is shown generally at 10 in Fig. 1, a dilation catheter and sheath assembly embodying the present invention in a preferred form. The sheath 12 is advantageously a substantially rigid, axially elongate hollow shaft throughout most of its length, but having a flexible distal tip 14. The sheath 12 exhibits an inner surface 16 which is substantially ellipsoid in cross-section, and is adapted to receive and guide an axially elongate catheter 18 and an endoscope 20 longitudinally therethrough. Advantageously, the particular endoscope used is known as a cystoscope.

In one embodiment of the invention, a cylindrical housing 22, disposed near the base of the sheath, exhibits a pair of grooves 24, formed upon two flattened surfaces 26 of the cylindrical housing 22, on opposite sides thereof. An end view of the cylindrical housing 22, as shown in Fig. 4, illustrates the ellipsoid shape of the inner walls 16 of the sheath 12, and the flattened side surfaces 26 thereof. A U-shaped clip 28 is integrally connected to the top of an inflation device 30 and is adapted to removably receive and retain the cylindrical housing 22 so as to enable the device 10 to be operated by one person, without the need for assistance. The removable attachment of the sheath 12 to the U-shaped clip 28 is illustrated in Figure 2. A C-shaped clip 32 may also be provided on the body of the inflation device 30, to removably receive and retain the catheter 18 therein and provide additional support for the proximal end of the device, thus controlling the catheter so it does not interfere with the eyepiece of the endoscope.

Situated on the underside 36 of the cylindrical housing 22 is a drainage port 38, having a cock valve 40 secured therein. The cock valve 40 is adapted to allow back-flowing fluids to escape the sheath 12 when positioned in the "on" position, and to prohibit the release of

such fluids when in the "off" position.

The cylindrical housing 22 includes a hub portion 42, disposed at the proximal end thereof. A rubberized septum 44, preferably formed from a silicon rubber compound, is detachably placed onto the hub 42 of the cylindrical housing 22 so as to provide a seal therefor. As best seen in Figures 3 and 3a, the septum 44 is a circular cap 46, having a pair of boot sleeves 48, 50 integrally connected to the proximal end of the cap 46. In one embodiment, the septum 44 exhibits an outwardly extending boot sleeve 48 an inwardly extending boot sleeve 50. The boot sleeves 48, 50 are adapted to receive the cystoscope lens 20 and the dilation catheter 18, and provide the septum 44 with elasticity at the point of contact therebetween. Without the presence of such sleeves, the rubberized septum 44 would itself deform if a force were applied to either the catheter 18 or cystoscope lens 20, thereby detracting from the septum's sealing ability. Further, the boot sleeves 48, 50 are adapted to readily adjust to and grip the outer diameter of the catheter 18 and lens 20 to yield a good seal therebetween. In an alternative embodiment, as shown in Figure 3a, both of the boot sleeves 52, 54 extend outwardly from the septum cap 44. This embodiment is possible only when there exists sufficient room on the outside of the septum, such that a sharing of a common wall between the two sleeves is not necessitated.

As best seen in Figure 11, the dilation catheter 18 of the present invention comprises an axially elongate catheter shaft 56, having a tapered guiding end 58, and a plurality of parallel conduits disposed therein. Situated near the guiding end 58 of the catheter shaft 56 is a locating balloon 60. The locating balloon 60 is a small latex Foley-type balloon, adapted for inflation by a source of pressurized fluid. Adjacent the locating balloon 60 is a larger dilation balloon 62, having a proximal shoulder 64 and a distal shoulder 66.

A feature of this invention is that the distal shoulder 66 of the dilation balloon 62 is overlapped by a portion of the locating balloon 60, such that, when the balloons are expanded, a minimal valley is left between the two balloons. Both of the balloons 60, 62 are bonded to the outer perimeter of the catheter shaft 56 by suitable adhesive or thermal process. In a similar manner, more than one axially adjacent dilation balloons can be provided on the dilation catheter, each provided with a unique inflation lumen extending through the catheter to a selectively controllable pressure source. The use of two or three or more dilation balloons permits control over the effective length of the dilation region of the catheter, as will be understood by one of skill in the art.

While the overlap of the locating balloon 60 onto the shoulder 66 of the dilation balloon 62 increases the area of dilation by minimizing the distance between the locating balloon 60 and the dilation balloon 62, suboptimal dilation of the affected prostatic urethra 68 still exists due to the tapered nature of expandable balloons, commonly used in dilation processes. To achieve optimal dilation near the ends 70, 72 of the affected prostatic urethra 68, the dilation balloon 62 can be molded with a steep, squared off end 74, as illustrated in Figure 13. Depending on the nature of the affected area of the prostatic urethra 68, it may be desirable to enable urethral dilation very close to the bladder neck 72 or the external sphincter muscle 70. Accordingly, either end of the dilation balloon 62, neither end, or both ends may be provided with a substantially vertical configuration as illustrated in Figures 13, 14 and 17.

A material which is well adapted to construction of the dilation balloon 62 of the present invention is polyethylene terephthalate (PET), such as KODAK's 9921 (TM). Preferably, the balloon 62 is extruded in a straight pipe configuration and then stretched and blown under high temperature and pressure to yield the desired shape 74. This type of technique is commonly applied in the making of angioplasty balloons. It should be noted that the PET material used to construct the dilation balloon exhibits superior tensile strength characteristics to that of materials used in manufacturing other types of dilation balloons, for example older angioplasty balloons. The PET material used to construct the dilation balloon of the present invention has a tensile strength of between 1.4×10^8 and 3.5×10^8 Nm^{-2} (20,000 and 50,000 psi), and is rated to withstand at least 3 bar (atmospheres) of pressure, and as much as 5 bar (atm).

If a rubberized latex material were used to fabricate the dilation balloon of the present invention, the walls of the balloon would necessarily be much thicker in order to withstand the exceedingly high pressures required for adequate dilation of the affected prostatic urethra. Thus, the PET material, by virtue of its superior strength, allows a thinner balloon to be utilized. The thinness of the balloon thus formed, makes possible a dilation balloon 62 which, in an uninflated state, conforms to the external walls of the catheter shaft 56, thereby providing a dilation catheter 18 having substantially the same size and shape as the unstretched lumen. However, the increased strength of the material also dictates a balloon which is somewhat stiff and substantially less pliable than a latex balloon.

Consequently, when negative pressure is applied to collapse the dilation balloon 62 made of the PET material, sharp ridges may form on the exterior surface thereof. Advantageously, the distal tip 14 of the introduction sheath 12 is formed of a flexible material, which readily deforms to the gross contours of the deflated dilation balloon 62, so as to coerce the balloon 62 into the introduction sheath 12 prior to the withdrawal of the catheter 18 from the urethra. Preferably, the tip 14 is formed from a substantially malleable Poly Vinyl Chloride (PVC) compound, which is RF welded to rigid shaft portion 12 of the sheath.

To ensure that the catheter 18 is fully within the introduction sheath 12 prior to the withdrawal thereof a second, visible indicator, such as the marking 78 on the exterior shaft 56 of the catheter 18 is provided. As the catheter shaft 56 and deflated dilation balloon 62 are gradually withdrawn from the urethra, the marking 78

will be advanced out of the sheath 12. When the designated marking 78 becomes visible, the catheter 18 is fully retracted within the sheath 12, and the device 10 may be withdrawn, without causing undue trauma to the urethral lumen.

As best seen in cross-section in Figure 10, the catheter shaft 56 houses a pair of circular inflation conduits 80, 82 and an irrigation conduit 84. The inflation conduit 80 having an aperture 86 underlying the locating balloon 60 exhibits a tubular passageway which permits pressurized fluid to be transmitted into the chamber enclosed by the locating balloon 60 , so as to selectively inflate the balloon 60 to a suitable level. Likewise, the inflation conduit 82 having a pair of inflation apertures 90, 92 underlying the dilation balloon 62 allows pressurized fluid to selectively fill the balloon 62 to a desired level.

To facilitate inflation of the locating balloon 60, a simple fluid valve 94 may be connected to the proximal end of the conduit 80. This valve 94 is integrally connected to the inflation conduit 80 and may be easily manipulated to allow quick sealing of the conduit 80 and maintain the pressurized fluid within the balloon chamber 60 and the conduit 80. The locating balloon 60 may be pressurized by inserting a hypodermic syringe (not shown) into the valve 94, with the valve 94 in its open condition. By forcing fluid into the conduit 80, the locating balloon 60, at the distal end of the inflation conduit will be inflated. The valve 94 may then be closed, and the hypodermic syringe removed, leaving the locating balloon 60 in an inflated state.

Since inflation of the dilation balloon 62 is more critical, the source of pressurized fluid 98 used to inflate the dilation balloon 62 is connected to a pressure gauge 100. Preferably, the inflation device 98 includes a syringe barrel 102 having a threaded rod and ratchet mechanism 104 which replaces the conventional plunger. This configuration allows fine tuning of the pressure amassed within the dilation balloon 62 by screw turning the threaded rod 104. It has been determined that an intra-balloon pressure of approximately 3 bar (atm.) (or 45 p.s.i.g.)is sufficient to force the prostate away from the urethral lumen to relieve the obstruction and reestablish normal micturition.

As a further alternative, the dilation catheter of the present invention can be configured to carry an expandable implantable stent over the dilation region thereof. This embodiment of the present invention would permit both expansion of the urethra and leaving behind of an expanded intraluminal support to ensure long-term patency of the urethra. The use of such implantable stents is disclosed in detail in U.S. Patent No. 4,762,128 issued to Robert F. Rosenbluth on August 9, 1988.

The catheter comprises a radially expandable region near the distal end thereof which, in its unexpanded state, has an outer diameter that is preferably slightly smaller than the outer diameter of the adjacent region of the catheter. Thus, the collapsed expandable region forms the bottom of an annular depression about the catheter.

The stent is removably, coaxially disposed about the expandable region of the catheter and within the annular depression formed therearound, and is controllably radially outwardly expandable in response to pressure from the expandable region of the catheter. When the stent is coaxially disposed about the expandable region of the catheter, and in an unexpanded state, the outer diameter of the unexpanded stent is approximately the same as or less than the outer diameter of the adjacent region of the catheter. Preferably, the distal end of the catheter comprises a flexible, resilient material in a shape to facilitate insertion into and negotiation of a collapsed lumen with minimal trauma to the lining thereof. Alternatively, for use with an introduction sheath, the stent may extend radially outwardly of the adjacent catheter shaft in the unexpanded state.

The radially outwardly expandable tubular stent for restoring patency to a collapsed portion of the urethral lumen comprises a material that is compatible with the urethral environment, and is capable of remaining in its expanded state following removal of the expansion catheter described above, thereby holding open the lumen of the urethra against a restricting pressure, such as that exerted by a hypertrophied prostate gland. The cross section of the expanded stent may be circular, or may also be a non-circular configuration which more closely corresponds to the shape of the normal lumen within the urethra. One embodiment of the stent in its expanded state comprises a substantially uniform cross-sectional area throughout its axial length. In another embodiment, the stent comprises a smaller cross-sectional area at its axial ends than in the central region thereof. In addition, the axial end regions of the stent may comprise a flexible material, or may taper in a radial inward direction thereby easing the transition from the lumen of the stent to the lumen of the urethra.

Referring to Figures 11 and 16, near the proximal end of the dilation balloon 62, and encircling the proximal shoulder 64 thereof, is a heavy black line 106 for use with the cystoscope embodiment of the present invention. Prior to inflating the dilation balloon 62, care should be taken to ensure that the black line 106 does not extend onto any portion of the external urethral sphincter muscle 108. This is vitally important as accidental dilation of the sphincter 108 may cause the patient to lose voluntary control over micturition, especially if the sphincter experiences plastic deformation, i.e., the inability to return to its original shape.

A further feature of this invention is the provision of an irrigation system. As described below, the system provides the dual features of both flushing blood away from the lens of the cystoscope to aid in the viewing of the external sphincter muscle and the black line 106 on the shoulder 64 of the dilation balloon 62 and inhibiting coagulation of blood within the urethra. This flushing system includes a plurality of irrigation ports 110 disposed along the exterior shaft 56 of the catheter 18, proximate to the line 106 are provided. The irrigation

ports 110 are adapted to continuously flush fluid, for example, saline, from the irrigation conduit 84, which extends through the center of the catheter shaft 56. The irrigation conduit 84 is provided with a coupling device 112 at the proximal end thereof, adapted to receive a source of flushing fluid, which, for example, can be a hanging container of saline (not shown), having a length of flexible tubing extending therefrom, for connection to the coupling device 112. The source of fluid is elevated and allowed to flow by gravity through the irrigation conduit 84 and out the irrigation ports 110, so as to flush blood away from the lens 20 and allow the urologist an unobstructed view of the external sphincter muscle 108 and the line 106 encircling the proximal shoulder 64 of the dilation balloon 62.

In addition to permitting an unobstructed view of the proximal shoulder 64 of the balloon 62, the flushing of blood inhibits coagulation, and therefore substantially eliminates clotting within the urethral lumen. Back-flowing flushing fluid and blood is drained from the urethra through introduction sheath 12 by gravity flow. A drainage reservoir (not shown) is connected to the cock valve 40 which, when in its open position, allows the back-flowing fluids to drain, by gravity flow, into the reservoir and subsequently disposed of. Alternatively, the flushing fluid can be supplied through the sheath 12 to flush blood away from the cystoscope lens 20. In this embodiment, the irrigation ports 110 of the irrigation conduit 84 function as influent ports to drain the flushing fluid and blood out of the urethra.

Located at the proximal end of the catheter shaft 56, and integrally connected thereto, is a Y-shaped plastic manifold 118. The manifold 118 is adapted to define and separate the trio of conduits 80, 82, 84 disposed within the body of the catheter shaft 56. Preferably, the manifold 118 is preformed in the Y-shaped configuration and is adapted to connect to the catheter shaft 56 and trio of conduits at the proximal end thereof. The catheter shaft 56 should be bent and cut to expose the inflation conduits 80, 82 respectively. The irrigation conduit 84 need not be exposed in this manner, as the manifold 118 includes a substantially straight portion in which the proximal end of the irrigation conduit 84 will reside. As shown in Figure 9, during the molding process flexible core pins 122, 124 are inserted into the exposed inflation conduits 80, 82 to respectively maintain the openings into the inflation conduits and provide support therefor during the molding process. In a similar manner, a straight core pin 126 is inserted into the irrigation conduit 84, and the catheter 18 is set into the preformed plastic manifold 118. Plastic is then injected into the manifold 118 to form a tight seal, and the core pins 122, 124, 126 are removed after the plastic has hardened.

In accordance with a further embodiment of the present invention, a source of pulsatile pressure (not illustrated) is provided for inflating the dilation balloon. Pumps capable of generating a variable frequency pulsatile pressure are well known in the art, and can readily be constructed by a cam-driven piston pump, as will be appreciated by one of skill in the art. By introducing and withdrawing fluid through the dilation port of the catheter, the balloon can be made to pulse at a desired frequency, Preferably, a pulsatile pressure source is connected to the dilation balloon which is capable of vibration at about the natural body frequency of approximately 8 Hz. High frequency pulsation of the balloon can be accomplished by providing an acoustic transducer on the dilation catheter, such as within the dilation balloon, and driven by an external variable frequency source of acoustic vibration. However, lower or higher frequencies such as from 1/60 Hz to as high as 5000 Hz may also facilitate reduction of the symptoms of obstructive prosthetism.

In accordance with a further embodiment of the dilation catheter of the present invention, illustrated in Figure 18, there is provided a dilation catheter 170, having a dilation balloon 172, or other dilation means thereon, which is provided at its distal end 174 with an integrally moulded, or otherwise secured, obturator 176 for facilitating introduction of the dilation catheter within the urethra. The obturator 176 may be moulded or formed from any of a variety of materials which are substantially biologically inert in the urethral environment, and which facilitate secure bonding to the material of the dilation catheter shaft 170 so that the obturator 176 will not become detached from the shaft in use. For example, a polyvinylchloride (PVC) obturator may be securely bonded to a PVC catheter shaft.

The dilation catheter 170 having an integral obturator 176 thereon is used together with an introduction sheath 178. For this purpose, the proximal end 180 of the integral obturator 176 is tapered slightly as illustrated in Figure 19, so that it may be snugly fitted within the distal end of the introduction sheath 178.

An integral obturator 176 can also be configured like the obturator 148 in Figure 7 and 8, with a more gradual taper to co-operate with flexible tip 14 of sheath 12. In addition, as with the flexible distal tip 14 illustrated in Figure 5, sheath 178 can be further provided with a flexible region 179 for receiving proximal end 180 when the catheter is in the retracted position.

Following introduction of the sheath 178 in accordance with the present embodiment of the invention, the dilation catheter 170 and integral obturator 176 may be extended distally relative to sheath 178 to expose the dilation means 172. The dilation means is then positioned in accordance with any of the positioning techniques described herein, and dilation is accomplished. Following dilation, the dilation means is reduced in external diameter, and the dilation catheter is retracted axially into the sheath so that the proximal end 180 of the obturator 176 fits snugly within the distal end of the sheath 178.

Referring to Figures 19 and 20, there is illustrated a locking bridge 186 for facilitating control over the various components of the dilation assembly, according to one embodiment of the present invention. Dilation catheter 182 is illustrated as extending through a dilation assem-

bly housing 184 in a manner similar to that discussed in connection with Figure 1. Dilation catheter 182 is additionally illustrated as extending through a tubular channel 183 contained in locking bridge 186, enabling a variety of securing functions as will be discussed.

A first locking means 188, such as a thumb screw 190, is provided on the locking bridge 186, for securing the locking bridge 186 with respect to the dilation catheter 182. Although illustrated as a thumb screw 190, the first securing means 188 may comprise any of a variety of means well known to one of skill in the art which may be adapted for securing locking bridge 186 against axial movement along dilation catheter 182.

Locking bridge 186 is further provided with a second tubular channel 192 for receiving a standard cystoscope therethrough. Channel 192 is provided with a second securing means 194 for securing the endoscope with respect to locking bridge 186. As discussed in connection with first securing means 188, the second securing means 194 can be any of a variety of means known in the art for securing a tubular member against axial motion through the locking bridge 186.

For example, referring to Figure 20, the second securing means 194 can comprise a rotatable sleeve 196 having a lever 198 thereon to facilitate rotation. The sleeve 196 is threadedly engaged with the body of locking bridge 186, and rotation of sleeve 196 provides a compressive retention force on an elongate body extending through channel 192, such as by compression of an annular ring of elastomeric material, or radial inward movement of a multiple jaw chuck, as are well known in the art. Locking bridge 186 is preferably additionally provided with a further securing means (not illustrated) for securing locking bridge 186 to the dilation assembly housing 184. This further securing means may comprise any of a variety of securing means, as will be appreciated by one of skill in the art.

The foregoing structures enable the clinician to fix the axial position of the dilating means in relation to the sheath, to fix the position of the locating means with respect to the sheath and to alternatively fix the position of the locating means with respect to the dilating means.

Method of Using the Dilation Catheter

Prior to dilating the obstructed urethral lumen, the length of the affected prostatic urethra 68 should be measured. This may be accomplished by the use of a calibration catheter 128, as illustrated in Figure 15. The calibration catheter 128 is an axially elongate shaft 130, having an expandable balloon 132 located near the distal end 134 thereof, and an inflation conduit (not shown) which extends substantially the entire length of the shaft 130. The expandable balloon 132 is adapted to be inflated through an inflation aperture 136, extending from the inflation conduit by a source of pressurized fluid (not shown). A plurality of graduated markings 138 extend along the exterior shaft 130 of the catheter 128, commencing near the proximal end 140 of the expandable balloon 132, and are adapted to be read from the distal end 134 of the catheter 128 to the proximal end 142.

The calibration catheter 128 is adapted to be received into the sheath of a standard cystoscope, and the cystoscope inserted into the urethra through the penile meatus. Once the distal end 134 and expandable balloon 132 of the calibration catheter 128 enters the bladder 144, the expandable balloon 132 may be inflated, and the catheter 128 slowly withdrawn from the urethra until the balloon 132 becomes lodged within the bladder neck 72. Graduated markings 138, inscribed on the exterior shaft 130 of the catheter 128 can be used to measure the distance between the bladder neck 72 and the lower end 70 of the affected prostatic urethra 68. Once such a measurement has been determined, the expandable balloon 138 may be deflated, and the catheter 128 withdrawn.

An introduction sheath 12, as illustrated in Figures 7 and 8 is then readied for insertion through the external urethral opening. An obturator 146, as shown in Figures 6, 7 and 8, having a smooth, tapered end 148 with no sharp edges is inserted into the sheath 12, and secured to the hub 42 of the cylindrical housing 22 by chamfered clips 150. The flexible tip 14 of the sheath 12 tapers inwardly, so as to grip the extending portion of the obturator 146 and provide a fairly smooth surface continuation of the introduction sheath. This mild transition between the obturator 146 and sheath 12 is instrumental in reducing damage and trauma to the tender urethral lumen. Once the sheath 12 has been fully inserted within the urethral lumen, the chamfered clips 150 may be released, and the obturator 146 withdrawn.

A catheter shaft 56, having a dilation balloon 62 with a length approximately equivalent to that measured by the calibration catheter 128, is then inserted through one 48 of two boot sleeves of the septum 44, until at least that portion of the catheter shaft 56 to which the expandible balloons 60, 62 are attached extends therethrough. The septum 44 is then friction fit onto the hub 42 of the cylindrical housing 22 such that the catheter 18 is in alignment with the larger diameter ellipsoid section 152 of the sheath 12. The cystoscope lens 20 is then inserted into the other boot sleeve 50, and is then urged through the sheath 12 and into the urethra after placement of the catheter 18.

To provide support for the catheter 18, an elongate stylet 154 may be inserted into the irrigation conduit 84, as illustrated in Figure 11. The stylet 154 facilitates the ease with which the catheter 18 may be inserted into the urethra, and may remain within the irrigation conduit 84 until the locating balloon 60 is disposed within the bladder 144, at which time the stylet 154 should be removed. Once the locating balloon 60 is within the bladder 144, the inflation conduit 80 may be coupled to a source of pressurized fluid so as to inflate the locating balloon 60. The catheter 18 is then gradually withdrawn from the bladder 144 until the balloon 60 is lodged within the bladder neck 72. When the locating balloon

60 is properly positioned within the neck 72 of the bladder 144, a seal is formed therebetween which prohibits fluids accumulating within the bladder 144 from travelling down the urethra and also prohibits fluids from flowing into and filling up the bladder from the urethra.

Once the catheter 18 has been properly situated with respect to the upper end 72 of the affected prostatic urethra 68, the irrigation conduit 84 may be connected to a source of flushing fluid. The flushing fluid is gravity fed through the irrigation conduit 84 and out the irrigation ports 110, so as to wash existent blood away from the cystoscope lens 20 and provide the urologist with an unobstructed view of the proximal shoulder 64 of the dilation balloon 62, and adjacent organs. Looking through the cystoscope, the urologist can manipulate the catheter 18 to confirm that the dilation balloon 62 is clear of the external urethral sphincter muscle 108, so as to ensure that the sphincter 108 will not inadvertently be dilated.

Upon properly positioning the dilation balloon 62 with respect to both the bladder neck 72 and the sphincter 108, the inflation conduit 82 for the dilation balloon 62 may be connected to a source of pressurized fluid 98. As described above, the inflation source 98 should enable a accurate, progressive dilation under constant control of the pressure being applied within the dilation balloon 62. The device remains within the affected prostatic urethra 68, until sufficient pressure dilation has been achieved. Subsequent to attaining adequate pressure dilation of the prostatic urethra, and eliminating the urinary outflow obstruction, the balloons 60, 62 may be deflated, releasing the pressurized fluid therefrom.

As the dilation balloon 62 is deflated, sharp ridges may form on the outer surface thereof, due to the stiffness of the material from which it was formed. As shown in Figure 5, the flexible tip 14 of the introduction sheath 12 readily deforms and flares, so as to coerce the dilation balloon 62 back into the sheath 12. When the marking 78, indicative of the time at which the dilation balloon 62 is completely within the sheath 12 becomes visible, the device may be withdrawn from the urethra.

In view of the medical treatment to be administered in using the device of the present invention, it is necessary that the device be aseptically clean. Accordingly, the dilation catheter and sheath can be cleansed and sterilized readily and easily either prior to use thereof, or packaged in this condition, available for immediate use. Further, both the catheter and sheath may be discarded after use, negating the need for recleaning and resterilization.

It will be appreciated that certain structural variations may suggest themselves to those skilled in the art. The foregoing detailed description is to be clearly understood as given by way of illustration only.

For example, the black line 106 as a visible indicator could be replaced by a radial enlargement of the dilation catheter, and this radial enlargement could comprise a radially outwardly extending annular ridge on the surface of the dilation catheter.

Claims

1. An intraluminal dilation apparatus (10) for relieving flow obstructions within the urethra comprising an axially elongate introduction sheath (12, 178), adapted for insertion into the urethra, a cystoscope (20), an axially elongate dilation catheter (18, 170), having a shaft (56), a distal end (58, 174) and at least one dilation means (62, 172) secured thereto, wherein said axially elongate dilation catheter (18, 170) extends through and is axially movable within said axially elongate introduction sheath (12, 178), to permit positioning of said dilation means (62, 172) within the urethra, characterised by:

   a peripheral line or a radial enlargement is positioned as a visible indicator (106) on said axially elongate dilation catheter (18, 170) near the proximal end of the dilation means (62, 172) such that said visible indicator (106) can be seen through said cystoscope (20) and the position of the visible indicator (106) provides an indication of the position of said dilation means (62,172) relative to an anatomical landmark.

2. An intraluminal dilation apparatus (10) as in Claim 1, having the said radial enlargement which comprises a radially outwardly extending annular ridge.

3. An intraluminal dilation apparatus (10) as in Claim 1, further comprising a locking bridge (186) having a first securing means (188) on the locking bridge (186) for fixing the position of the dilation means (62, 172) relative to the locking bridge (186).

4. An intraluminal dilation apparatus (10) as in Claim 3, further comprising a second securing means (194) on the locking bridge (186) for fixing the position of the cystoscope relative to the locking bridge (186).

5. An intraluminal dilation apparatus (10) as in Claim 1, further comprising an obturator (146, 148, 176) for facilitating introduction of the dilation means (172) into the urethra.

6. An intraluminal dilation apparatus (10) as in Claim 5, wherein said obturator (176) is integral with said axially elongate dilation catheter (18, 170) at said distal end (58, 174).

7. An intraluminal dilation apparatus (10) as in Claim 5, wherein said obturator (146, 148) is tapered for fitting within said distal end of said axially elongate introduction sheath (12, 178).

8. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate introduction sheath (12, 178) further comprises a flexible distal tip (14, 179).

9. An intraluminal dilation apparatus (10) as in Claim 8, wherein said flexible distal tip (14, 179) readily deforms the contours of said dilation means (62, 172) when said dilation means (62, 172) is not dilated.

10. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate introduction sheath (12) has an inner surface (16) which is substantially ellipsoid in cross-section and is adapted to receive and guide said axially elongate dilation catheter (18, 170) and said cystoscope (20).

11. An intraluminal dilation apparatus (10) as in Claim 1, further comprising an inflatable locating balloon (60) distally located on said axially elongate dilation catheter (18, 170).

12. An intraluminal dilation apparatus (10) as in Claim 11, wherein said dilation means (62, 172), further comprises a distal shoulder or end (66, 74), and wherein said locating balloon (60) overlaps a portion of said distal shoulder (66, 74).

13. An intraluminal dilation apparatus (10) as in Claim 1, wherein said dilation means (62, 172) further comprises a proximal shoulder or end (64) and a distal shoulder or end (66, 74), and wherein either or both of said proximal shoulder (64) and said distal shoulder (66, 74) are squared off.

14. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate dilation catheter (18, 170) has an irrigation conduit (84) and at least one irrigation port (110) proximate to the visible indicator (106).

15. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate dilation catheter (18, 170) has a second visible indicator (78) that becomes visible to the operator during withdrawal of said axially elongate dilation catheter (18, 170) when said dilation means (62, 172) is fully retracted within said axially elongate introduction sheath (12, 178).

16. An intraluminal dilation apparatus (10) as in Claim 15, wherein the second visible indicator (78) comprises a line.

17. An intraluminal dilation apparatus (10) as in Claim 1, wherein said axially elongate dilation catheter (18, 170) further comprises an expandable implantable stent over said dilation means (62, 172).

18. An intraluminal dilation apparatus (10) as in Claim 17, wherein said expandable implantable stent has an outer diameter that is equal to or smaller than an outer diameter of said axially elongate dilation catheter (18, 170) adjacent to said stent, when said stent is in an unexpanded state.

19. An intraluminal dilation apparatus (10) as in Claim 1, wherein said dilation means (62, 172) is dilated by a pulsatile pressure source.

Patentansprüche

1. Intraluminale Dilatationsvorrichtung (10) zum Beseitigen von Flußbehinderungen in der Harnröhre mit einer axialen, länglichen Einführungshülse (12, 178), die zur Einführung in die Harnröhre geeignet ist, einem Zystoskop (20), einem axialen, länglichen Dilatationskatheter (18, 170) mit einem Schaft (56), einem körperfernen Ende (58, 174) und wenigstens einer Dilatationseinrichtung (62, 172), die an ihm befestigt ist, wobei der axiale längliche Dilatationskatheter (18, 170) sich durch die axiale längliche Einführungshülse (12, 178) hindurcherstreckt und in dieser axial beweglich ist, um die Positionierung der Dilatationseinrichtung (62, 172) in der Harnröhre zu ermöglichen, dadurch gekennzeichnet, daß eine periphere Linie oder eine radiale Vergrößerung als ein sichtbarer Indikator (106) an dem axialen, länglichen Dilatationskatheter (18, 170) in der Nähe des körpernahen Endes der Dilatationseinrichtung (62, 172) positioniert ist, so daß der sichtbare Indikator (106) durch das Zystoskop (20) gesehen werden kann und die Position des sichtbaren Indikators (106) eine Anzeige der Position der Dilatationseinrichtung (62, 172) relativ zu einer anatomischen Kennungsmarke bildet.

2. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die radiale Vergrößerung vorgesehen ist und eine sich radial nach außen erstrekkende ringförmige Rippe umfaßt.

3. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei ferner eine Sperrbrücke (186) mit einer ersten Befestigungseinrichtung (188) an der Sperrbrücke (186) zur Festlegung der Position der Dilatationseinrichtung (62, 172) relativ zu der Sperrbrücke (186) vorgesehen ist.

4. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 3, wobei ferner eine zweite Befestigungseinrichtung (194) an der Sperrbrücke (186) zur Festlegung der Position des Zystoskops relativ zu der Sperrbrücke (186) vorgesehen ist.

5. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei ferner ein Obturator (146, 148, 176) zur Erleichterung der Einführung der Dilatationseinrichtung (172) in die Harnröhre vorgesehen ist.

6. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 5, wobei der Obturator (176) einstückig mit dem axialen länglichen Dilatationskatheter (18, 170) an dem körperfernen Ende (58, 178) ausgebildet ist.

7. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 5, wobei der Obturator (146, 148) sich zum Einsetzen in das körperferne Ende der axialen länglichen Einführungshülse (12, 178) verjüngt.

8. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die axiale längliche Einführungshulse (12, 178) ferner eine flexible körperferne Spitze (14, 179) aufweist.

9. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 8, wobei die flexible körperferne Spitze (14, 179) die Konturen der Dilatationseinrichtung (62, 172) leicht deformiert, wenn die Dilatationseinrichtung (62, 172) nicht vergrößert ist.

10. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die axiale längliche Einführungshülse (12) eine Innenfläche (16) aufweist, die einen im wesentlichen ellipsoidischen Querschnitt besitzt und den axialen länglichen Dilatationskatheter (18, 170) und das Zystoskop (20) aufnehmen und führen kann.

11. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, die ferner einen aufblasbaren Lokalisierungsballon (60) aufweist, der körperfern an dem axialen länglichen Dilatationskatheter (18, 170) angeordnet ist.

12. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 11, wobei die Dilatationseinrichtung (62, 172) ferner eine körperferne Schulter oder ein körperfernes Ende (66, 74) aufweist und wobei der Lokalisierungsballon (60) einen Bereich der körperfernen Schulter (66, 74) überlappt.

13. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die Dilatationseinrichtung (62, 172) ferner eine körpernahe Schulter oder ein körpernahes Ende (64) und eine körperferne Schulter oder ein körperfernes Ende (66, 74) aufweist und wobei entweder die körpernahe Schulter (64) und die körperferne Schulter (66, 74) oder die körpernahe Schulter (64) oder die körperferne Schulter (66, 74) rechteckig ausgestellt sind.

14. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei der axiale längliche Dilatationskatheter (18, 170) eine Spühlleitung (84) und wenigstens eine Spühlöffnung (110) nahe am sichtbaren Indikator (106) aufweist.

15. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei der axiale längliche Dilatationskatheter (18, 170) einen zweiten sichtbaren Indikator (78) aufweist, der für den Operateur während des Zurückziehens des axialen länglichen Dilatationskatheters (18, 170) sichtbar wird, wenn die Dilatationseinrichtung (62, 172) vollständig in die axiale längliche Einführungshülse (12, 178) zurückgezogen ist.

16. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 15, wobei der zweite sichtbare Indikator (78) eine Linie umfaßt.

17. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei der axiale längliche Dilatationskatheter (18, 170) ferner über der Dilatationseinrichtung (62, 172) eine expandierbare implantierbare Aufspannungseinrichtung aufweist.

18. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 17, bei der die expandierbare implantierbare Aufspanneinrichtung einen Außendurchmesser besitzt, der gleich oder kleiner als der Außendurchmesser des axialen länglichen Dilatationskatheters (18, 170) in der Nähe der Aufspanneinrichtung ist, wenn die Aufspanneinrichtung nicht expandiert ist.

19. Intraluminale Dilatationsvorrichtung (10) nach Anspruch 1, wobei die Dilatationseinrichtung (62, 172) durch eine pulsierende Druckquelle vergrößert wird.

Revendications

1. Appareil de dilatation intraluminale (10) pour réduire les obstructions à la circulation à l'intérieur de l'urètre, comprenant une gaine d'introduction (12, 178) à élongation axiale, adaptée pour l'insertion dans l'urètre, un cystoscope (20), un cathéter de dilatation (18, 170) à élongation axiale ayant un axe (56), une extrémité distale (58, 174) et au moins un moyen de dilatation (62, 172) qui lui est fixé, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale s'étend à travers et est mobile axialement à l'intérieur de ladite gaine d'introduction (12, 178) à élongation axiale, pour permettre le positionnement dudit moyen de dilatation (62, 172) à l'intérieur de l'urètre, caractérisé en ce que :

une ligne périphérique ou un élargissement radial est positionné comme indicateur visible (106) sur ledit cathéter de dilatation (18, 170) à élongation axiale, près de l'extrémité proximale du moyen de dilatation (62, 172) de telle façon que ledit indicateur visible (106) puisse être vu à travers ledit cystoscope (20) et la position de l'indicateur visible (106) fournit une indication de la position dudit

moyen de dilatation (62, 172) par rapport à un point de repère anatomique.

2. Appareil de dilatation intraluminale (10) selon la revendication 1, ayant ledit élargissement radial qui comprend un bord annulaire s'étendant dans le sens radial, vers l'extérieur.

3. Appareil de dilatation intraluminale (10) selon la revendication 1, comprenant en outre un pont de blocage (186) ayant un premier moyen de sécurité (188) pour fixer la position du moyen de dilatation (62, 172) par rapport au pont de blocage (186).

4. Appareil de dilatation intraluminale (10) selon la revendication 3, comprenant en outre un deuxième moyen de sécurité (194) sur le pont de blocage (186) pour fixer la position du cystoscope par rapport au pont de blocage (186).

5. Appareil de dilatation intraluminale (10) selon la revendication 1, comprenant en outre un obturateur (146, 148, 176) pour faciliter l'introduction du moyen de dilatation (172) dans l'urètre.

6. Appareil de dilatation intraluminale (10) selon la revendication 5, dans lequel ledit obturateur (176) est solidaire avec ledit cathéter de dilatation (18, 170) à élongation axiale et ladite extrémité distale (58, 174).

7. Appareil de dilatation intraluminale (10) selon la revendication 5, dans lequel ledit obturateur (146, 148) est taillé en cône pour s'adapter à l'intérieur de ladite extrémité distale de ladite gaine d'introduction (12, 178) à élongation axiale.

8. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ladite gaine d'introduction (12, 178) à élongation axiale comprend en outre une extrémité distale flexible (14, 179).

9. Appareil de dilatation intraluminale (10) selon la revendication 8, dans lequel ladite extrémité distale flexible (14, 179) déforme facilement les contours dudit moyen de dilatation (62, 172) lorsque ledit moyen de dilatation (62, 172) n'est pas dilaté.

10. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ladite gaine d'introduction (12) à élongation axiale comporte une surface intérieure (16) qui a une section ellipsoïdale, et qui est adaptée pour recevoir et guider ledit cathéter de dilatation (18, 170) à élongation axiale et ledit cystoscope (20).

11. Appareil de dilatation intraluminale (10) selon la revendication 1, comprenant un ballon de localisation (60) gonflable placé de manière distale sur ledit cathéter de dilatation (18, 170) à élongation axiale.

12. Appareil de dilatation intraluminale (10) selon la revendication 11, dans lequel ledit moyen de dilatation (62, 172) comprend en outre un épaulement ou une extrémité distale (66, 74) et dans lequel ledit ballon de positionnement (60) recouvre une partie dudit épaulement distal (66, 74).

13. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit moyen de dilatation (62, 172) comprend en outre un épaulement ou une extrémité (64) proximale et un épaulement ou une extrémité distale (66, 74) et dans lequel l'un ou l'autre, ou les deux épaulements proximaux (64) et ledit épaulement distal (66, 74) sont placés en équerre.

14. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale comporte un conduit d'irrigation (84) et au moins un port d'irrigation (110) proches de l'indicateur visible (106).

15. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale comporte d'un deuxième indicateur visible (78) qui devient visible pour l'opérateur pendant le retrait dudit cathéter de dilatation (18, 170) à élongation axiale quand ledit moyen de dilatation (62, 172) est totalement rétracté à l'intérieur de ladite gaine d'introduction (12, 178) à élongation axiale.

16. Appareil de dilatation intraluminale (10) selon la revendication 15, dans lequel ledit deuxième indicateur visible (78) comprend une ligne.

17. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit cathéter de dilatation (18, 170) à élongation axiale comporte en outre un stent implantable et extensible au-dessus dudit moyen de dilatation (62, 172).

18. Appareil de dilatation intraluminale (10) selon la revendication 17, dans lequel ledit stent implantable et extensible a un diamètre extérieur égal ou plus petit qu'un diamètre extérieur dudit cathéter de dilatation (18, 170) à élongation axiale adjacent audit stent, quand ledit stent est dans un état non dilaté.

19. Appareil de dilatation intraluminale (10) selon la revendication 1, dans lequel ledit moyen de dilatation (62, 172) est dilaté par une source de pression à pulsations.

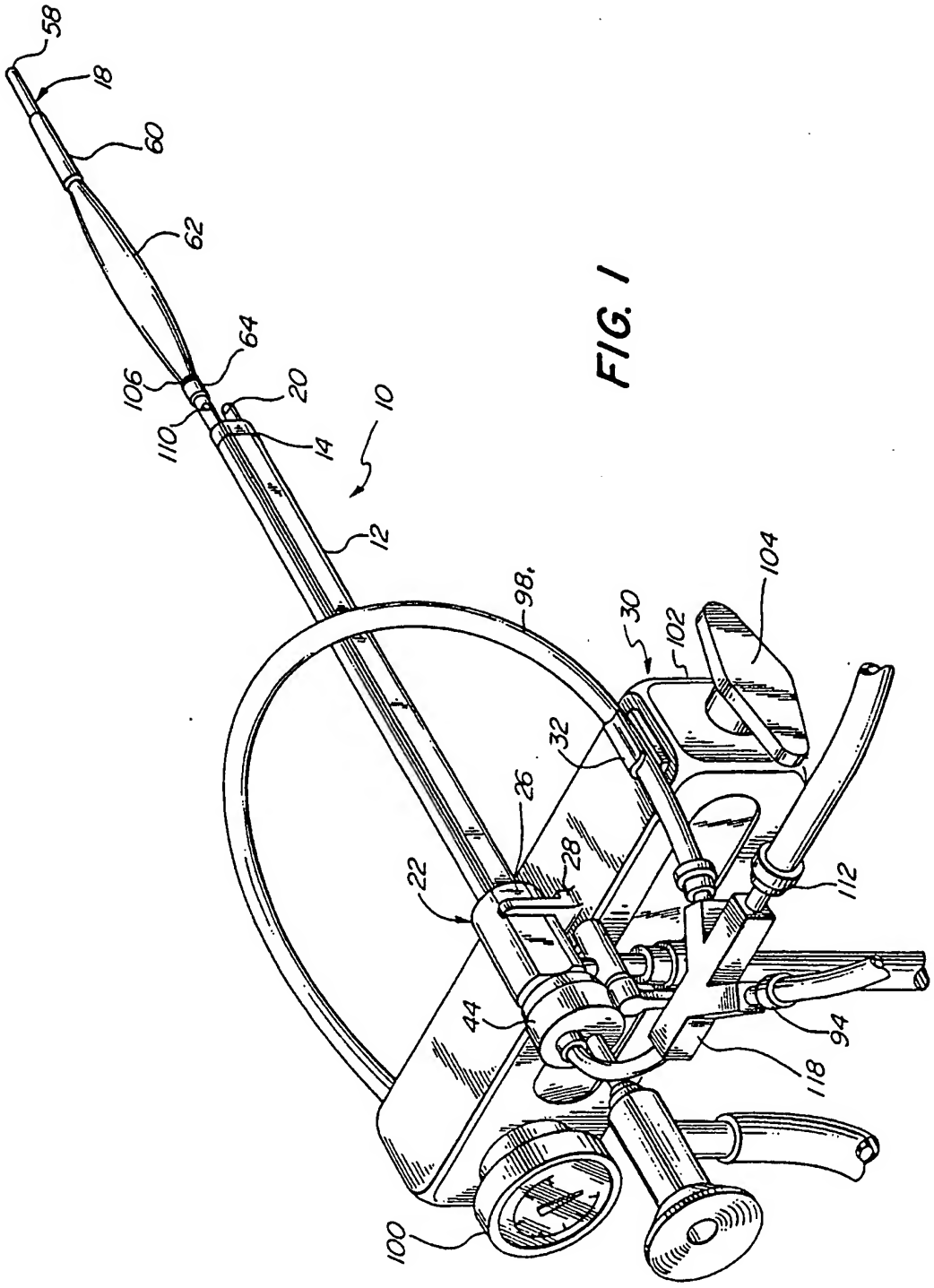

58
18
60
62
64
106
110
20
14
10
12
98
30
102
104
32
26
28
22
112
44
94
118
100

FIG. 1

FIG. 2

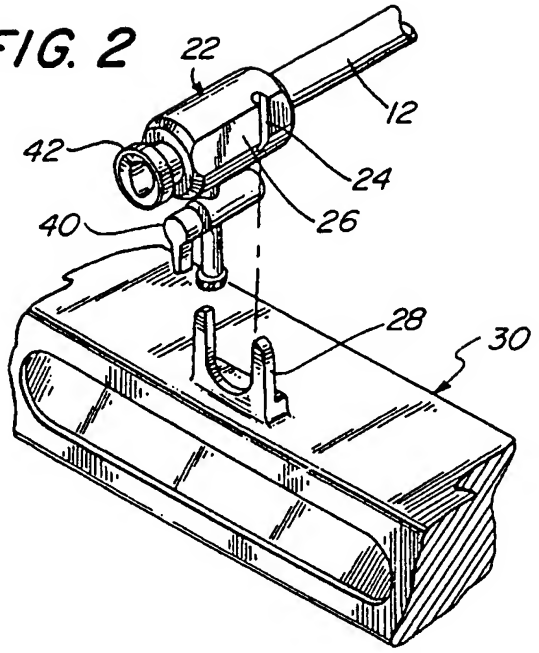


FIG. 3

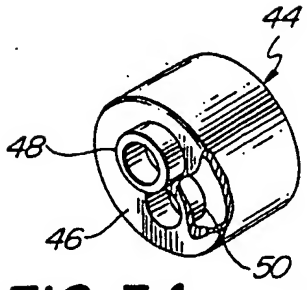


FIG. 3A

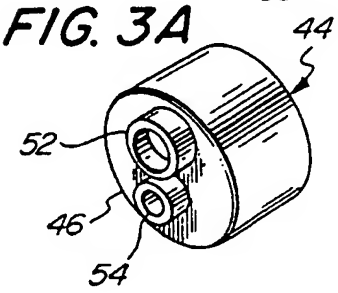


FIG. 4

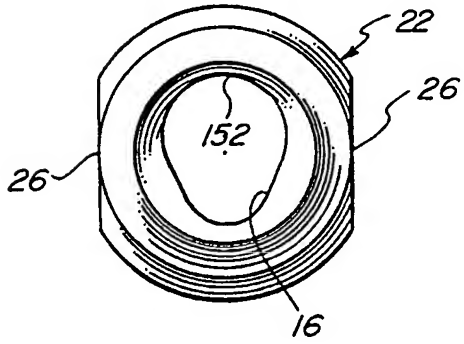


FIG. 5

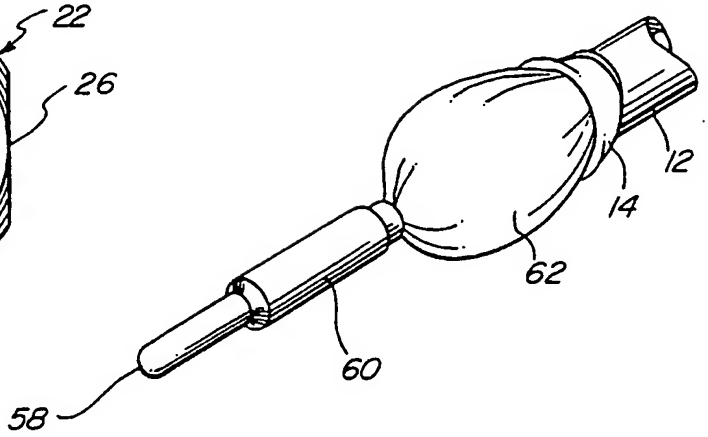
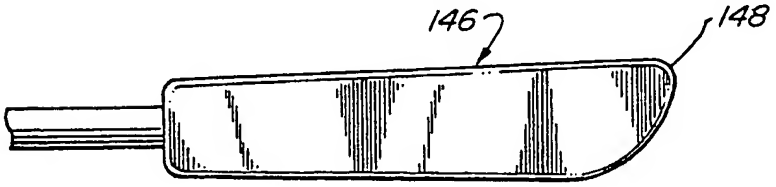


FIG. 6



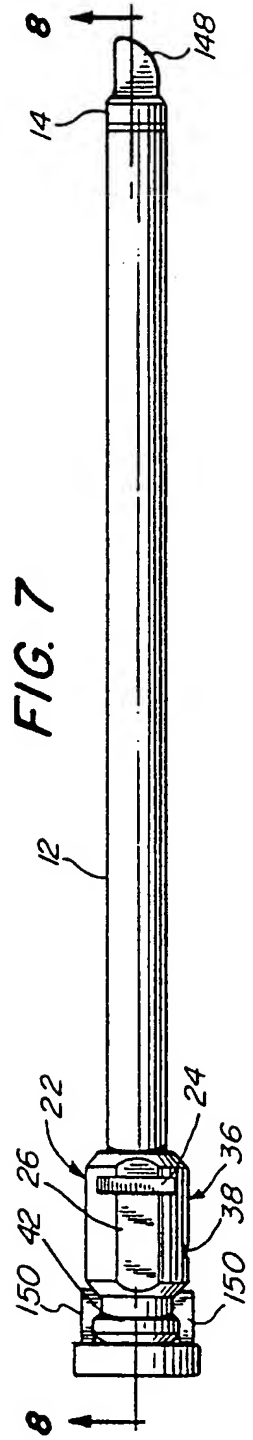


FIG. 7

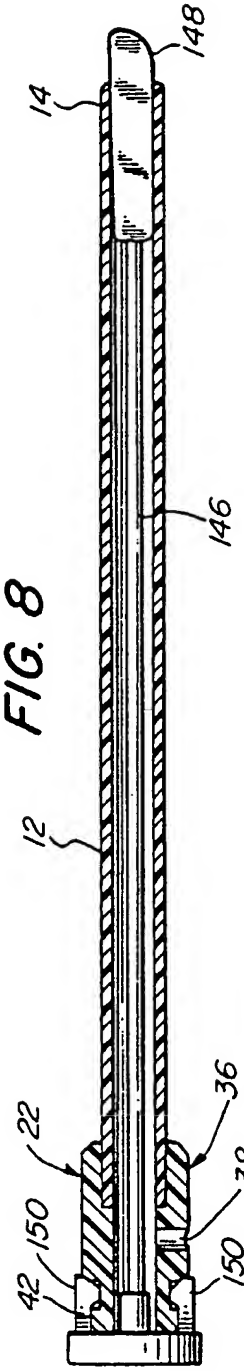


FIG. 8

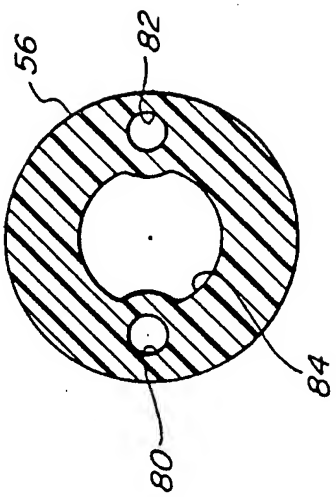


FIG. 10

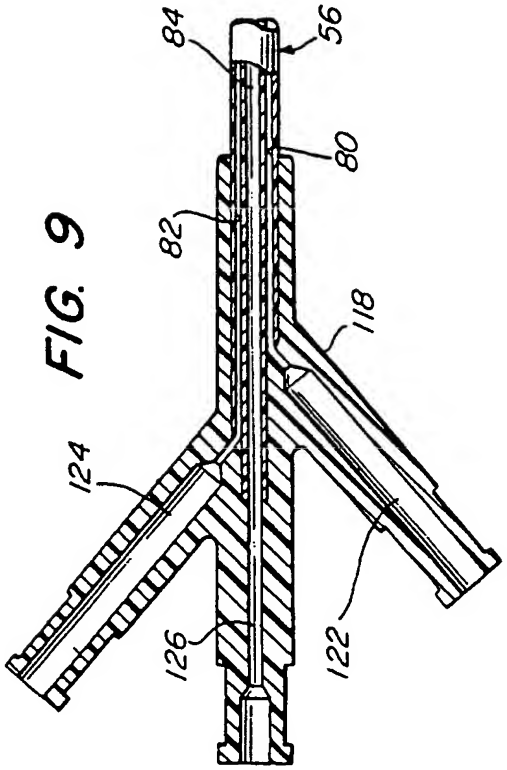


FIG. 9

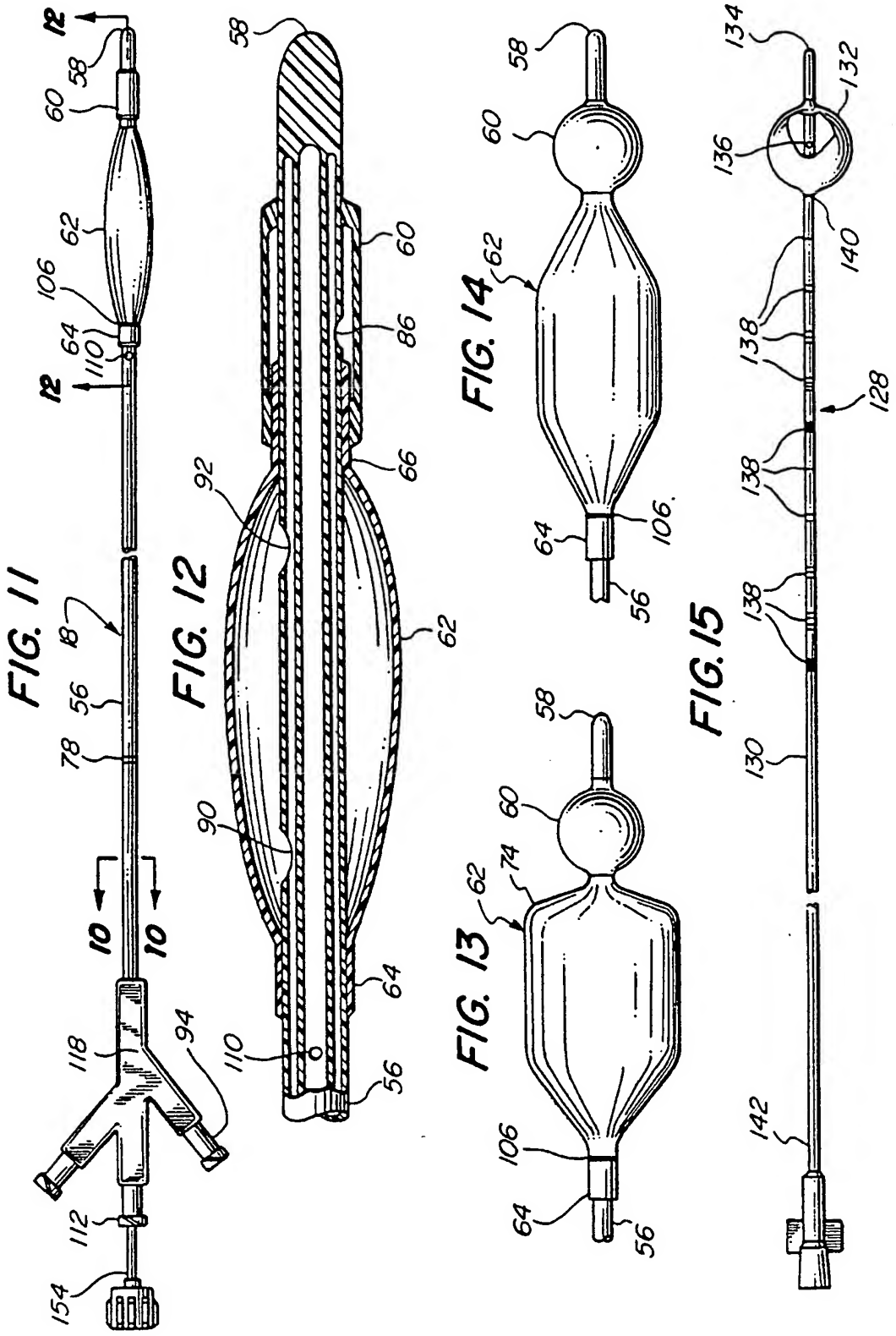


FIG. 11
12
58
60
62
106
64
110
12
18
56
78
10
10
118
94
112
154
FIG. 12
58
60
86
66
92
62
90
64
110
56
FIG. 14
58
60
62
64
106
56
FIG. 13
58
60
74
62
106
64
56
FIG. 15
134
132
136
140
138
128
138
138
130
142

FIG. 16

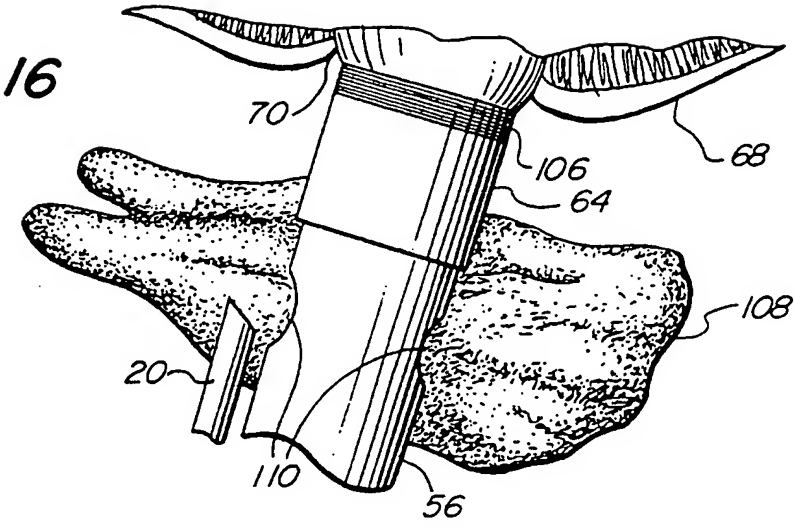
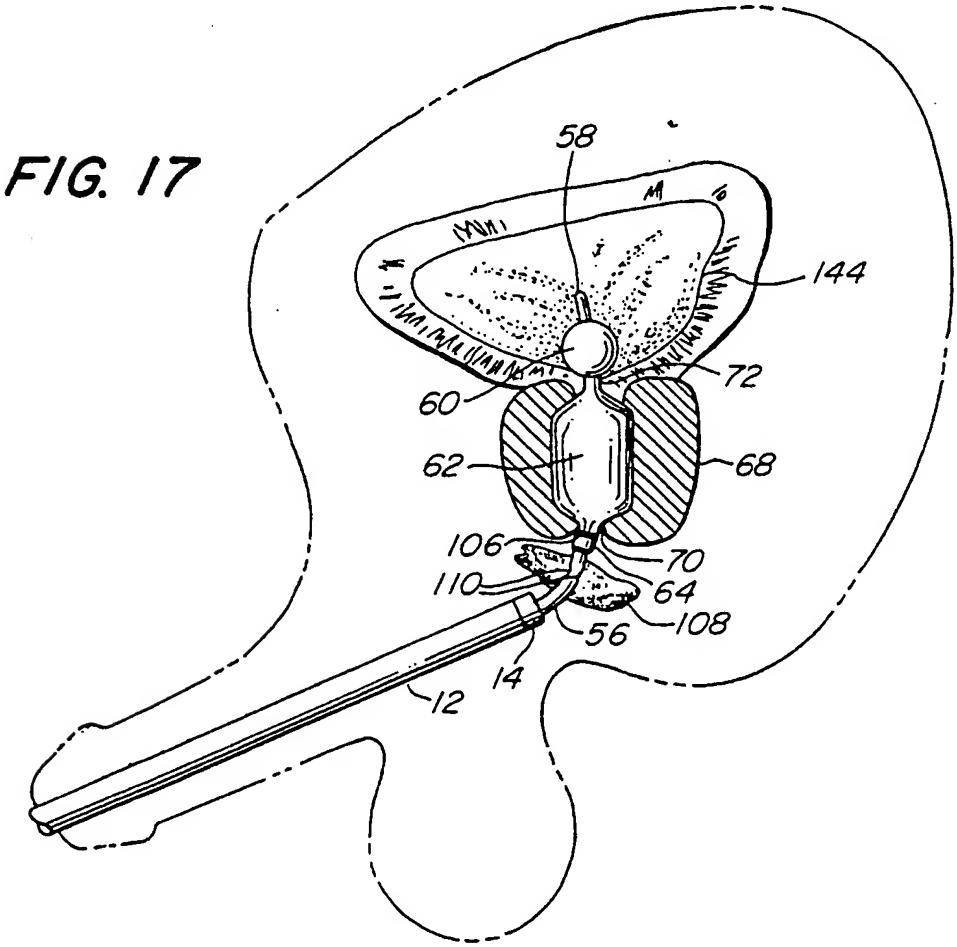

70
68
106
64
108
20
110
56

FIG. 17


58
144
72
60
62
68
106
70
110
64
108
56
14
12

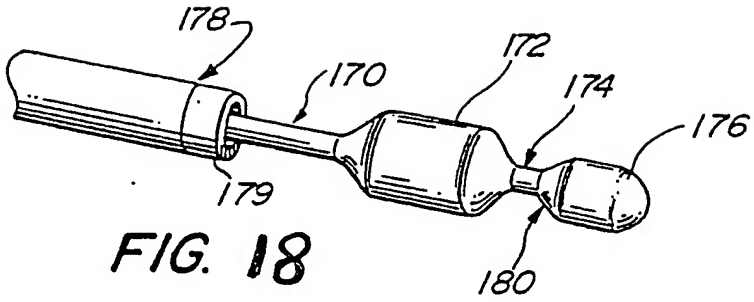


FIG. 18

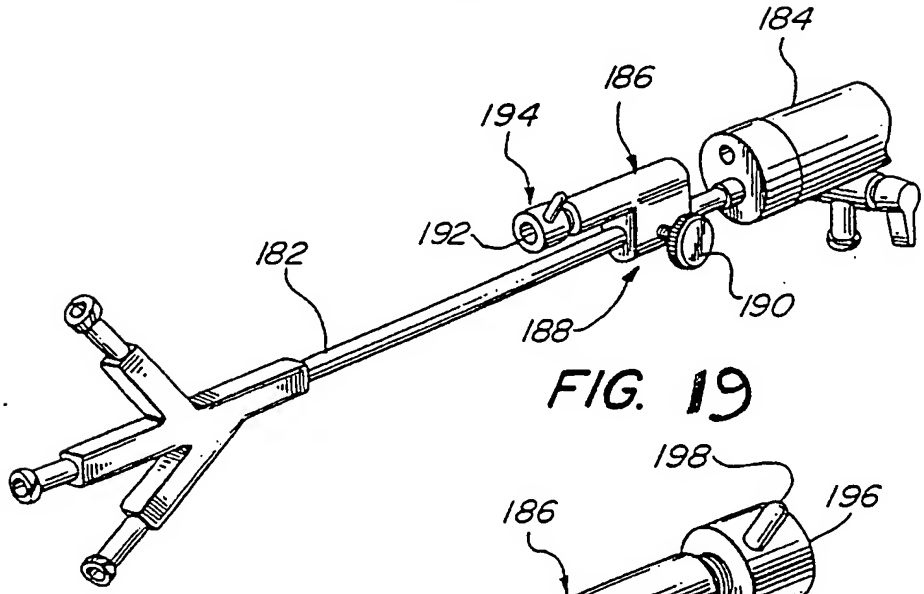


FIG. 19

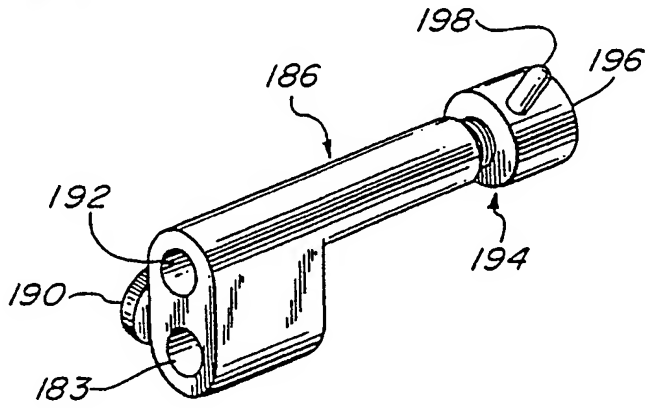


FIG. 20

BC

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 506 920 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
09.04.1997 Bulletin 1997/15

(21) Application number: **91918535.5**

(22) Date of filing: **03.09.1991**

(51) Int. Cl.[6]: **A61M 25/00**, A61F 5/453, A61F 5/455, A61M 25/10

(86) International application number:
PCT/US91/06228

(87) International publication number:
WO 92/06731 (30.04.1992 Gazette 1992/10)

(54) URINARY CONTROL WITH INFLATABLE SEAL

URINKONTROLLE MIT AUFBLASBARER DICHTUNG

MAITRISE DE L'INCONTINENCE URINAIRE A L'AIDE D'UN JOINT GONFLABLE

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

(30) Priority: **22.10.1990 US 600629**

(43) Date of publication of application:
07.10.1992 Bulletin 1992/41

(73) Proprietor: **SALAMA, Fouad A.**
West Des Moines, IA 50265 (US)

(72) Inventor: **SALAMA, Fouad A.**
West Des Moines, IA 50265 (US)

(74) Representative: **Desaix, Anne et al**
Ernest Gutmann - Yves Plasseraud S.A.
3, rue Chauveau-Lagarde
75008 Paris (FR)

(56) References cited:
WO-A-82/03557
US-A- 3 459 175
US-A- 3 707 146
US-A- 3 811 448
US-A- 3 841 304
US-A- 4 626 250
US-A- 4 710 169
US-A- 4 813 935

EP 0 506 920 B1

Printed by Rank Xerox (UK) Business Services
2.14.1/3.4

Description

Incontinence is a problem for many people including older adults. Present day approaches to dealing with incontinence such as the Foley catheter often times causes urinary tract infection. A bag for urine is required and smell becomes a problem. The chances of infection are increased each time the bag is changed. The cost for the Foley catheters and pads is substantial. An inflatable conventional spherical balloon is used to keep the catheter in the bladder, but leakage around the catheter occurs and is a problem. It was not an object of this product to provide a seal around the catheter at the bladder orifice.

US-A-4.813.935 discloses a urinary control system comprising a balloon having a toroid shape when inflated. This shape provided a contact between the balloon and the bladder of the Foley catheter type.

WO-82/03557 discloses a urinary catheter balloon having a shape substantially corresponding to the shape of the bladder to prevent contact between a catheter tip and the inner wall of the bladder.

A urinary control system comprising an inner balloon is also known from US-A-384.304. However, in this system the balloon is spherical and has to be pulled tightly against the inner urethra opening.

The present invention aims to overcome the drawbacks of the prior art by providing a simple inexpensive device for controlling urine flow in the urethra, which is compatible to the body and will not cause discomfort, infection and pass urine only through operation of the valve rather than around the outside of the catheter.

More precisely, the present invention relates to a urinary control system comprising an air line having an inflatable balloon at one end and an air inlet at the opposite end, the balloon being adapted to be inserted in a bladder neck through an urethra orifice of an urethra, a urine tube positioned in parallel relationship with said line and adapted to receive urine from the bladder, and seal means connected to said line adapted to maintain said balloon inflated,

said urinary control system being characterized in that the balloon, when inflated, has a generally pear shape corresponding to the shape of the bladder at the urethra orifice to sealingly engage the neck of the bladder to provide a seal around the urine tube in the bladder neck.

A valve may be provided in the urinary tube outside of the urethra.

An anchoring collar of hydrogel may frictionally engage the exterior of the urinary tube and is then positioned against the outer end of the urethra to hold the balloon in tight sealing engagement with the neck of the bladder.

The urinary control of this invention when used by a male may include the additional use of a support shell around the penis to stabilize the urinary tube which extends through the penis. The anchoring collar of hydrogel is positioned against the outer end of the support shell. The shell is one piece but includes a plurality of sections to allow for fitting the support shell to penises of different sizes. A collar of hydrogel is also placed between the inner end of the shell sections and the pubic bone base of the penis. An accordion type section is included to give the shell flexibility in accommodating penises of different lengths and to permit them to be disposed at varying angles to the body.

A hypodermic syringe or the like may function as an air pump when its needle is inserted into the air tube to inflate the balloon.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a fragmentary perspective view of the urinary control with inflatable seal.

Figure 2 is a longitudinal cross-sectional view of the urinary control in the urethra of a female.

Figure 3 is an enlarged cross-sectional view of the structure indicated by the line 3 - 3 in Figure 2.

Figure 4 is a cross-sectional view taken along line 4 - 4 in Figure 2 showing the valve in a closed condition.

Figure 5 is a view similar to Figure 4 but showing the valve in an open condition.

Figure 6 is a view similar to Figure 2 but showing the urinary control in the urethra of a male.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The urinary control of this invention is referred to generally by the reference numeral 10 as seen in Figure 1 and includes a urine tube 12 in which a valve 14 is connected. The tube 12 has an outer outlet end 15 and an inner inlet end 16 with sidewall openings 18.

An air tube 20 extends into the valve body 14 and along the length of the tube 12 towards the inlet end 16. The air tube 20 has an inlet end 22 and an outlet end 24 positioned in a balloon 26 formed in part by the sidewalls of the urine tube 14. Balloon chamber 28 is provided. The air tube outlet end includes an opening 30 in chamber 28.

The valve body 14 includes a pair of oppositely disposed blade elements 32 normally closed. Pressure on the opposite sidewalls of the valve body 14 will cause the valve elements 32 to spread as seen in Figure 5 and allow urine to flow toward the outlet end 15.

An anchoring collar means 36 of hydrogel is provided around the urine tube 12 outwardly of the balloon 26 and frictionally engages the outer surface of the urine tube 12 to hold the walls of the balloon 26 in tight sealing contact with the bladder orifice and neck 38 as seen in Figure 2. The balloon 26 is shaped to correspond to the shape of the inner side walls of the bladder at the orifice to provide a seal around the catheter thereby preventing leakage. This shape is generally pear shape. In the female, the collar 36 presses against the body around the opening to the urethra. A sleeve 42 also extends around the urine tube 12 and may be adjusted tightly against the collar 36 to assist in holding

the collar tight against the person's body at the outlet end of the urethra. Rounded serrations 44 are provided along the outside of the urine tube 12 and register with serrations on the inside face of the collar 36 and serve to hold the collar 36 in place in turn holding the balloon seal 26 in place thereby preventing leakage around the tube 12.

A hypodermic syringe 48 functions as an air pump and has a needle 50 which is inserted into the inlet end 22 of the air tube 20. The inlet end 22 has a passageway 52 normally closed except when opened by the needle 50 thereby allowing air to be introduced into the tube to fill the balloon 26 but when the needle 50 is removed the passageway is sealed preventing air from escaping and deflating the balloon.

When the urinary control of this invention is used on a male, a one piece support shell 60 is provided around the penis 62 and includes an outer section 64 having an outer end 64A being rounded to the curvature of the head of the penis. An accordion pleats section 64B interconnects the outer section 64 with a base section 64C. The base section 64C presses against a hydrogel collar 66 which presses against the base (pubic bone) 68 of the penis. A second hydrogel collar 70 is positioned against the outer end of the rounded section 64A to hold the urine tube 12 in place such that the balloon 26 when inflated is pressed against the bladder neck 38. Among the properties of hydrogel is that it is soft and pliable but yet firm.

In use it is seen that the urine tube 12 will be inserted into the urethra of the male or female far enough that the balloon 26 will be seated in the neck 38 of the bladder. Air is introduced into the air tube 20 through the use of a hypodermic syringe. A hydrogel collar is then positioned against the body at the outer end of the urethra to hold the balloon 26 in position to form a seal with the bladder neck 38. The balloon is inflated from the solid line position in Figure 2 to the dash line inflated condition. When fully installed, no urine can leak around the urine tube 12 due to the seal the balloon 26 provides with the bladder neck 38. Urine can enter the openings 18 in the inlet end 16 of the urine tube 12 and pass into the valve 14 and upon actuation of the valve blades 32 by applying pressure to opposite sides of the valve 14, the valve will be open for drainage of the bladder through the outlet end 15.

The valve 14 and urine tube 12 are formed from elastomer silicone material of a 50 or 55 durometer from Dow Corning, Midland, Michigan. The balloon 26 may have a capacity of approximately 40 cc's.

Claims

1. A urinary control system comprising an air line (20) having an inflatable balloon (26) at one end and an air inlet (22) at the opposite end, the balloon (26) being adapted to be inserted in a bladder neck (38) through an urethra orifice of an urethra, a urine tube (12) positioned in parallel relationship with said line (20) and adapted to receive urine from the bladder, and seal means (52) connected to said line adapted to maintain said balloon inflated,

   said urinary control system being characterized in that the balloon (26), when inflated, has a generally pear shape corresponding to the shape of the bladder at the urethra orifice to sealingly engage the neck of the bladder (38) to provide a seal around the urine tube (12) in the bladder neck (38).

2. The system of claim 1 and an anchoring means (36) on said air line (20) adapted to operatively engage the body at the outer end of the urethra to hold said balloon (26) tight against the neck of the bladder (38).

3. The system of claim 1 or 2 wherein said urine tube is formed from elastomer silicone material.

4. The system of claim 2 wherein said anchoring means (36) includes a shell (60) adapted to fit over the penis (62), said shell having inner and outer ends (64A) with the inner end adapted to operatively engage the pubic bone base (68) of the penis (62).

5. The system of claim 4 wherein said shell (60) includes a flexible and expandable section (64B) adapted to fit penises of different sizes and disposed at varying angles to the body.

6. The system of claim 5 wherein said flexible and expandable section (64B) is further defined as including accordion pleats.

7. The system of claim 1 wherein said anchoring means is an anchoring collar (36,70) provided to extend around the urine tube for being positioned at the outer end of the urethra to hold the balloon (26) in tight sealing contact with the bladder office.

8. The system of claim 7 wherein said collar (36,70) urine tube (12) have cooperating serrations to provide a tight fit therebetween and thereby limit relative movement therebetween.

9. The system of claim 8 wherein said collar (36,70) is made of a soft pliable material.

10. The system of claim 9 wherein said collar (36,70) is made of hydrogel material.

Patentansprüche

1. Urinsteuerungssystem, das eine Luftleitung (20) mit einem aufblasbaren Ballon (26) an einem Ende und einem Lufteinlaß (22) an dem gegenüberliegenden Ende aufweist, wobei der Ballon (26) zum

Einsetzen in einen Harnblasenhals (38) durch eine Harnröhrenöffnung einer Harnröhre angepaßt ist, ferner weist das Urinsteuerungssystem eine parallel zu der Leitung (20) angeordnete und zum Aufnehmen von Urin aus der Blase angepaßte Urinröhre (12), und mit der Leitung verbundene Dichtmittel (52), die zum Erhalten des aufgeblasenen Zustands des Ballons ausgebildet sind, auf, wobei das Urinsteuerungssystem dadurch gekennzeichnet ist, daß der Ballon (26) im aufgeblasenen Zustand im wesentlichen eine Birnenform aufweist, die der Form der Blase an der Harnröhrenöffnung entspricht, um dichtend mit dem Harnblasenhals (38) zusammenzuwirken, um eine Dichtung um die Urinröhre (12) herum im Harnblasenhals (38) zu bilden.

2. Urinsteuerungssystem nach Anspruch 1, wobei Befestigungsmittel (36) an der Luftleitung (20) zum Zusammenwirken mit dem Körper an dem äußeren Ende der Harnröhre angepaßt sind, um den Ballon (26) fest gegen den Harnblasenhals (36) zu halten.

3. Urinsteuerungssystem nach Anspruch 1 oder 2, wobei der Urinröhre ist von Silicon Elastomere Material ausgemacht.

4. Urinsteuerungssystem nach Anspruch 2, wobei die Befestigungsmittel (36) eine über den Penis (62) passende Hülle (60) aufweisen, die innere und äußere Enden (64A) aufweist, wobei das innere Ende zum Zusammenwirken der Schambeinbasis (68) des Penis (62) ausgebildet ist.

5. Urinsteuerungssystem nach Anspruch 4, bei dem die Hülle (60) einen flexiblen und auseinanderziehbaren Bereich (64B) aufweist, der zum Anbringen auf unterschiedlich großen und in verschiedenen Winkeln zu dem Körper angeordneten Penissen ausgebildet ist.

6. Urinsteuerungssystem nach Anspruch 5, bei dem der flexible und auseinanderziehbare Bereich (64B) Ziehharmonikafalten umfaßt.

7. Urinsteuerungssystem nach Anspruch 1, bei dem das Befestigungsmittel eine Befestigungsmanschette (36, 70) ist, die sich um die Urinröhre herum erstreckt, um an dem äußeren Ende der Harnröhre angeordnet zu werden, um den Ballon (26) in fester dichtender Berührung mit dem Harnblasenhals zu halten.

8. Urinsteuerungssystem nach Anspruch 7, bei dem die Manschette (36, 70) und die Urinröhre (12) zusammenwirkende Riffelungen aufweisen, um einen festen Sitz aneinander zu bewirken und so relative Bewegungen zueinander zu begrenzen.

9. Urinsteuerungssystem nach Anspruch 8, bei dem die Manschette (36, 70) aus einem weichen nachgiebigen Material gefertigt ist.

10. Urinsteuerungssystem nach Anspruch 9, bei dem die Manschette (36, 70) aus einem Hydrogelmaterial gefertigt ist.

Revendications

1. Système de maîtrise de l'incontinence urinaire comprenant une ligne d'air (20) ayant un ballon gonflable (26) à une extrémité et une entrée d'air (22) à l'extrémité opposée, le ballon (26) étant adapté pour être inséré dans un col de vessie (38) à travers un orifice urétéral d'un urètre, un tube pour l'urine (12) positionné parallèlement à ladite ligne (20) et adapté pour recevoir de l'urine provenant de la vessie, et un moyen de joint (52) connecté à ladite ligne adapté pour maintenir ledit ballon gonflé,

ledit système de maîtrise de l'incontinence urinaire étant caractérisé en ce que le ballon (26), une fois gonflé, a généralement une forme de poire, correspondant à la forme de la vessie au niveau de l'orifice urétéral pour engager par un joint étanche le col de la vessie (38) pour réaliser un joint étanche autour du tube pour l'urine (12) dans le col de la vessie (38).

2. Système selon la revendication 1, dans lequel un moyen d'ancrage (36) sur ladite ligne d'air (20) est adapté pour engager activement le corps au niveau de l'extrémité externe de l'urètre pour maintenir ledit ballon (26) fermement contre le col de la vessie (38).

3. Système selon la revendication 1 ou 2, dans lequel ledit tube pour l'urine est formé d'un matériau silicone élastomère.

4. Système selon la revendication 2, dans lequel ledit moyen d'ancrage (36) comporte une coquille (60) adaptée pour s'ajuster par-dessus le pénis (62), ladite coquille ayant des extrémités intérieure et extérieure (64A), l'extrémité intérieure étant adaptée pour engager activement la base osseuse pubienne (68) du pénis (62).

5. Système selon la revendication 4, dans lequel ladite coquille (60) comporte une section flexible et extensible (64B) adaptée pour s'ajuster à des pénis de différentes tailles et disposés suivant des angles variables par rapport au corps.

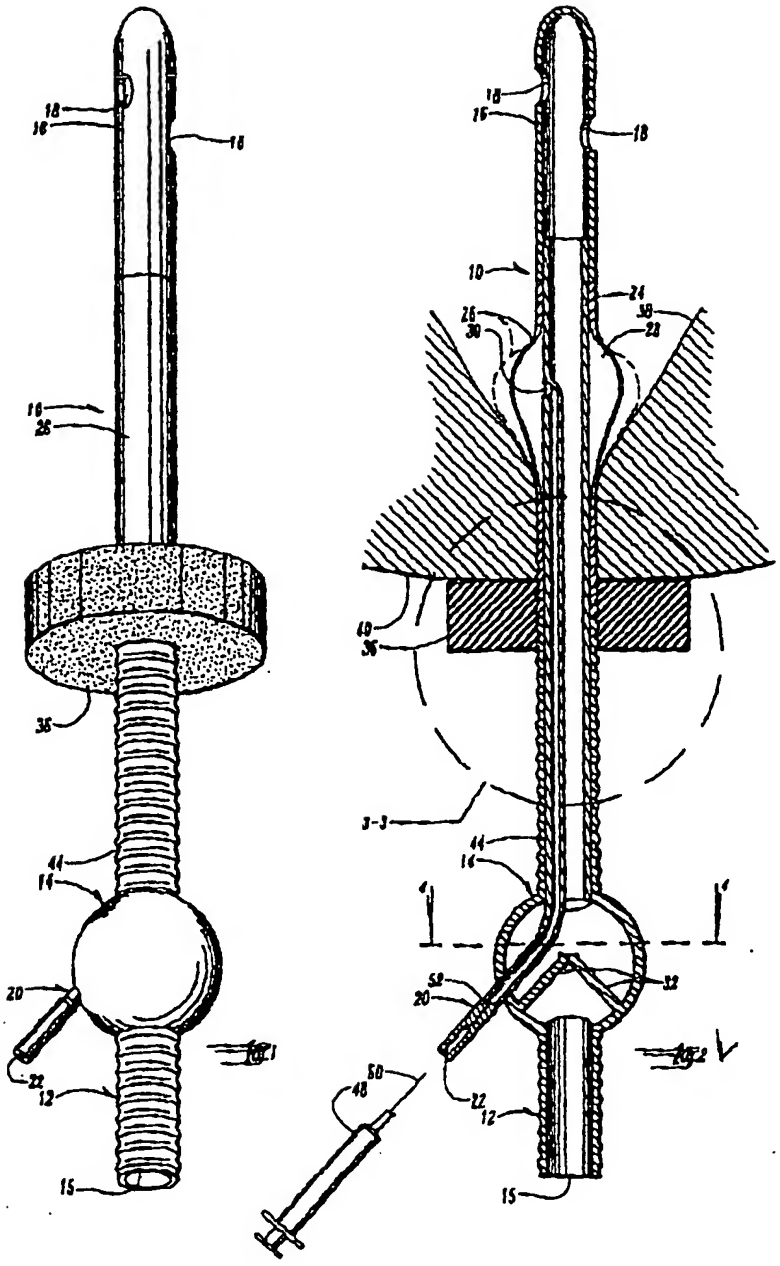
6. Système selon la revendication 5, dans lequel ladite section flexible et extensible (64B) est en outre définie comme comportant des plis en accordéon.

7. Système selon la revendication 1, dans lequel ledit moyen d'ancrage est une collerette d'ancrage (36, 70) prévue pour s'étendre autour du tube pour l'urine, à positionner au niveau de l'extrémité extérieure de l'urètre pour maintenir le ballon (26) fermement en contact à joint étanche avec l'orifice de la vessie.

8. Système selon la revendication 7, dans lequel ladite collerette (36, 70) et le tube pour l'urine (12) ont des indentations coopérantes pour fournir un ajustement serré entre eux et pour ainsi limiter tout mouvement relatif de l'un par rapport à l'autre.

9. Système selon la revendication 8, dans lequel ladite collerette (36, 70) est en matériau souple pliable.

10. Système selon la revendication 9, dans lequel ladite collerette (36, 70) est en matériau d'hydrogel.


18
16
18
10
24
26
30
28
38
40
36
3-3
44
14
4
4
20
50
32
22
12
48
50
15

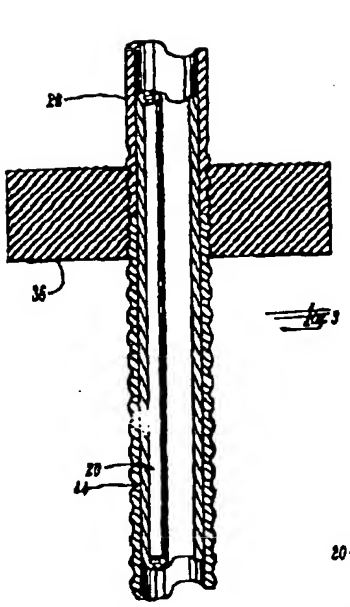


Fig 3

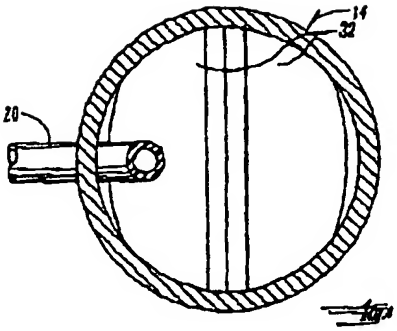


Fig 4

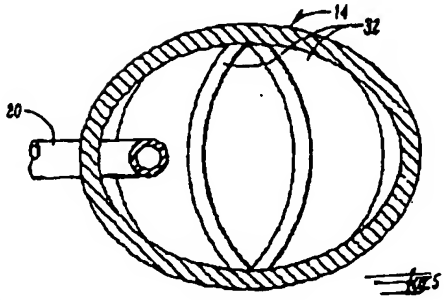


Fig 5

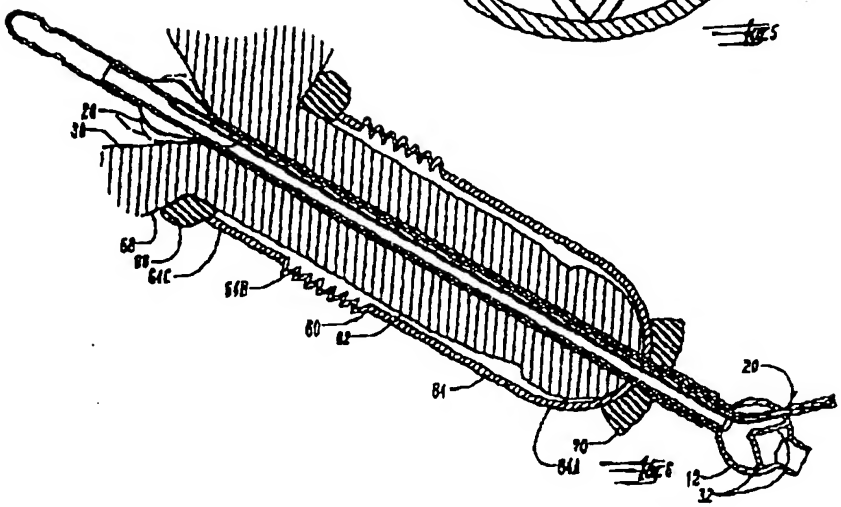


Fig 6

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 628 288 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
05.04.2000 Bulletin 2000/14

(51) Int. Cl.[7]: **A61B 18/12**, A61N 5/02

(21) Application number: **94303423.1**

(22) Date of filing: **12.05.1994**

(54) Medical probe

Medizinische Sonde

Sonde médicale

(84) Designated Contracting States:
DE FR GB

(30) Priority: **13.05.1993 US 61647**

(43) Date of publication of application:
14.12.1994 Bulletin 1994/50

(73) Proprietor: **VIDAMED, INC.**
Menlo Park, CA 94025 (US)

(72) Inventors:
- **Edwards, Stuart D.**
  Los Altos, California 94024 (US)
- **Lundquist, Ingemar H.**
  Pebble Beach, California 93953 (US)
- **Baker, James Allen, Jr.**
  Palo Alto, California 94306 (US)
- **Sharkey, Hugh, R.**
  Redwood City, California 94061 (US)
- **Lax, Ronald G.**
  Grass Valley, California 95945 (US)

(74) Representative:
Harrison, David Christopher et al
MEWBURN ELLIS
York House
23 Kingsway
London WC2B 6HP (GB)

(56) References cited:

EP-A- 0 219 216	EP-A- 0 521 595
WO-A-92/10142	WO-A-93/15664
WO-A-94/04220	GB-A- 618 528
US-A- 4 565 200	US-A- 4 920 978
US-A- 4 950 267	US-A- 4 966 597
US-A- 5 007 908	US-A- 5 122 138

EP 0 628 288 B1

Printed by Xerox (UK) Business Services
2.16.7 (HRS)/3.6

Description

[0001] This invention is directed to a device for penetrating body tissues for medical purposes such as tissue ablation and fluid substance delivery, for example. The device penetrates tissue to the precise target selected in order to deliver energy to the tissue and/or deliver substances. It limits this treatment to the precise preselected site, thereby minimizing trauma to normal surrounding tissue and achieving a greater medical benefit. This device is a catheter-like device for positioning a treatment assembly in the area or organ selected for medical treatment with one or more stylets in the catheter, mounted for extension from a stylet port in the side of the catheter through surrounding tissue to the tissue targeted for medical intervention.

[0002] Treatment of cellular tissues usually requires direct contact of target tissue with a medical instrument, usually by surgical procedures exposing both the target and intervening tissue to substantial trauma. Often, precise placement of a treatment probe is difficult because of the location of targeted tissues in the body or the proximity of the target tissue to easily damaged, critical body organs, nerves, or other components.

[0003] Benign prostatic hypertrophy or hyperplasia (BPH), for example, is one of the most common medical problems experienced by men over 50 years old. Urinary tract obstruction due to prostatic hyperplasia has been recognized since the earliest days of medicine. Hyperplastic enlargement of the prostate gland often leads to compression of the urethra, resulting in obstruction of the urinary tract and the subsequent development of symptoms including frequent urination, decrease in urinary flow, nocturia, pain, discomfort, and dribbling. The association of BPH with aging has been shown to exceed 50% in men over 50 years of age and increases in incidence to over 75% in men over 80 years of age. Symptoms of urinary obstruction occur most frequently between the ages of 65 and 70 when approximately 65% of men in this age group have prostatic enlargement.

[0004] Currently there is no proven effective non-surgical method of treatment of BPH. In addition, the surgical procedures available were not totally satisfactory. Patients suffering from the obstructive symptoms of this disease were provided with few options: continue to cope with the symptoms (i.e., conservative management), submit to drug therapy at early stages, or submit to surgical intervention. More than 430,000 patients per year undergo surgery for removal of prostatic tissue in the United States. These represent less than five percent of men exhibiting clinical significant symptoms.

[0005] Those suffering from BPH are often elderly men, many with additional health problems which increase the risk of surgical procedures. Surgical procedures for the removal of prostatic tissue were associated with a number of hazards including anesthesia related morbidity, hemorrhage, coagulopathies, pulmonary emboli and electrolyte imbalances. These procedures performed currently can also lead to cardiac complications, bladder perforation, incontinence, infection, urethral or bladder neck stricture, retention of prostatic chips, retrograde ejaculation, and infertility. Due to the extensive invasive nature of the treatment options for obstructive uropathy, the majority of patients delay definitive treatment of their condition. This circumstance can lead to serious damage to structures secondary to the obstructive lesion in the prostate (bladder hypertrophy, hydronephrosis, dilation of the kidney pelves, chronic infection, dilation of ureters, etc.) which is not without significant consequences. In addition, a significant number of patients with symptoms sufficiently severe to warrant surgical intervention are therefore poor operative risks and are poor candidates for prostatectomy. In addition, younger men suffering from BPH who do not desire to risk complications such as infertility are often forced to avoid surgical intervention. Thus the need, importance and value of improved surgical and non-surgical methods for treating BPH is unquestionable.

[0006] High-frequency currents are used in electrocautery procedures for cutting human tissue especially when a bloodless incision is desired or when the operating site is not accessible with a normal scalpel but presents an access for a thin instrument through natural body openings such as the esophagus, intestines or urethra. Examples include the removal of prostatic adenomas, bladder tumors or intestinal polyps. In such cases, the high-frequency current is fed by a surgical probe into the tissue to be cut. The resulting dissipated heat causes boiling and vaporization of the cell fluid at this point, whereupon the cell walls rupture and the tissue is separated.

[0007] Destruction of cellular tissues *in situ* has been used in the treatment of many diseases and medical conditions alone or as an adjunct to surgical removal procedures. It is often less traumatic than surgical procedures and may be the only alternative where other procedures are unsafe. Ablative treatment devices have the advantage of using an electromagnetic energy which is rapidly dissipated and reduced to a non-destructive level by conduction and convection forces of circulating fluids and other natural body processes.

[0008] Microwave, radiofrequency, acoustical (ultrasound) and light energy (laser) devices, and tissue destructive substances have been used to destroy malignant, benign and other types of cells and tissues from a wide variety of anatomic sites and organs. Tissues treated include isolated carcinoma masses and, more specifically, organs such as the prostate, glandular and stromal nodules characteristic of benign prostate hyperplasia. These devices typically include a catheter or cannula which is used to carry a radiofrequency electrode or microwave antenna through a duct to the zone of treatment and apply energy diffusely through the duct wall into the surrounding tissue in all

directions. Severe trauma is often sustained by the duct wall during this cellular destruction process, and some devices combine cooling systems with microwave antennas to reduce trauma to the ductal wall. For treating the prostate with these devices, for example, heat energy is delivered through the walls of the urethra into the surrounding prostate cells in an effort to ablate the tissue causing the constriction of the urethra. Light energy, typically from a laser, is delivered to prostate tissue target sites by "burning through" the wall of the urethra. Healthy cells of the duct wall and healthy tissue between the nodules and duct wall are also indiscriminately destroyed in the process and can cause unnecessary loss of some prostate function. Furthermore, the added cooling function of some microwave devices complicates the apparatus and requires that the device be sufficiently large to accommodate this cooling system.

[0009] More specifically in the prior art, US-A-4,565,200 discloses a radio frequency lesion electrode system having an insulated outer cannula through which the electrodes are fed. Temperature sensors may be provided. WO-A-92/10142 uses laser energy to treat tissue, the laser energy being supplied to the end of a catheter and needle system. Various lumina in the catheter terminate at the surface of the catheter. US-A-4,950,267 discloses a laser beam treatment device for an endoscope comprising a control section and an insertion section which includes a flexible tube portion, a bending portion and a distal end portion. EP-A-0521595 shows a torqueable catheter, through the lumen of which electrodes may be passed for treating tissues at the end of the catheter. The intermediate document WO-A-94/04220 discloses a medical probe device as defined in claim 1, in which, however, no second lumen is provided within the insulating sleeve.

[0010] Application of liquids to specific tissues for medical purposes is limited by the ability to obtain delivery without traumatizing intervening tissue and to effect a delivery limited to the specific target tissue. Localized chemotherapy, drug infusions, collagen injections, or injections of agents which are then activated by light, heat or chemicals would be greatly facilitated by a device which could conveniently and precisely place a fluid (liquid or gas) supply catheter opening at the specific target tissue.

OBJECTS AND SUMMARY OF THE INVENTION

[0011] It is an object of this invention to provide a device for penetrating tissue, through intervening tissues to the precise target tissue selected for a medical action such as tissue ablation and/or substance delivery, limiting this activity to the precise preselected site, thereby minimizing the trauma and achieving a greater medical benefit.

[0012] It is another object of this invention is to provide a device for tissue ablation of body tissues which delivers the therapeutic energy directly into targeted tissues while minimizing effects on its surrounding tissue.

[0013] It is a still further object of this invention is to provide a device for introducing fluid treatment agents such as flowable liquids and gases, with greater precision and ease to a specific location in the body.

[0014] Another object of this invention which may be embodied is to provide a thermal destruction device which gives the operator more information about the temperature and other conditions created in both the tissue targeted for treatment and the surrounding tissue. In addition, it will provide more control over the physical placement of the stylet and over the parameters of the tissue ablation process.

[0015] In summary, the medical probe device of this invention is as shown in claim 1. Preferably, at least one portion of an opposed surface of the electrode lumen and the electrode are spaced apart to define a liquid supply passageway for delivery of medicament liquid. A second optional fluid passage lumen terminates at a distal port in the distal end of the non-conductive sleeve and comprises means passing fluid therethrough.

[0016] A temperature sensor third lumen terminates in a sealed closure adjacent the distal end of the non-conductive sleeve. At least one and preferably a plurality of temperature sensing devices such as thermocouples are positioned in the third lumen, the leads extending through the lumen. One preferred embodiment has two temperature sensing devices positioned in the third lumen, one temperature sensing device being positioned within about 1 mm of the distal end of the non-conductive sleeve, and the second temperature sensing device being positioned at least 3 mm and preferably from 3 to 6 mm from the distal end of the non-conductive sleeve.

[0017] In summary, another embodiment of this invention comprises a catheter having a control end and a probe end, the probe end including a stylet guide housing having at a stylet port and stylet guide means for directing a flexible stylet outward through the stylet port and through intervening tissue to targeted tissues. A stylet is positioned in at least one of said stylet guide means, the stylet comprising an electrical conductor enclosed within a non-conductive sleeve. The electrode has a distal length having at least one current focusing groove means thereon and a distal tip shaped to focus current on its terminal end, whereby RF current passing therefrom into surrounding tissue forms a lesion extending outward from the groove and tip. In one preferred embodiment, the distal length has a plurality of annular focusing grooves or a spiral focusing groove thereon.

[0018] Preferably at least a part of the electrode is enclosed within a support tube having sufficient strength to maintain electrode linearity when the electrode is directed outward through the stylet port.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019]

Fig. 1 is an isometric view of an RF ablation catheter embodiment of this invention with an fiber optic viewing accessory.

Fig. 2 is a cross-sectional view of a catheter of Fig. 1 showing details of the stylet guide housing.

Fig. 3 is a side view of the stylet and lumen assembly of this invention.

Fig. 4 is a cross-sectional side view of the of the junction of the stylet and control tube assembly taken along the central axis of the tubing.

Fig. 5 is a cross-sectional view of the junction of the stylet and control tube assembly taken along the line 5-5 of Fig. 4.

Fig. 6 is a cross-sectional view of a trilumen stylet of this invention taken along the line 6-6 in Fig 3.

Fig. 7 is a cross-sectional side view of the trilumen stylet tip shown in Fig. 3 taken along line 7-7 of Fig. 6.

Fig. 8 is a plane view of the annular groove embodiment of the current density focusing electrode of this invention.

Fig. 9 is a plane view of the spiral groove embodiment of the current density focusing electrode of this invention. position and the sleeve partially retracted therefrom.

Fig. 10 is an exploded view of the RF ablation catheter shown in Fig. 1.

Fig. 11 is an isometric view of the adjuster block and tension tube assembly of the RF ablation catheter shown in Fig. 10.

Fig. 12 is a detailed view "A" of the tension tube connections shown in Fig. 11.

Fig. 13 is an exploded view of the sleeve and electrode slide block assembly of the embodiment shown in Fig. 10.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The device of this invention provides a precise controlled positioning of a treatment stylet in a tissue targeted for treatment, destruction or sampling from a catheter positioned in the vicinity of the target tissue.

[0021] The term "stylet" as used hereinafter is defined to include both solid and hollow probes which are adapted to be passed from a catheter port through normal tissue to targeted tissues. The stylet is shaped to facilitate easy passage through tissue. It can be a solid wire, thin rod, or other solid shape or it can be a thin hollow tube or other shape having a longitudinal lumen for introducing fluids to or removing materials from a site. The stylet can also be a thin hollow tube or other hollow shape, the hollow lumen thereof containing a reinforcing or functional rod or tube such as a laser fiber optic. The stylet preferably has a sharpened end to reduce resistance and trauma when it is pushed through tissue to a target site.

[0022] The stylet can be designed to provide a variety of medically desired treatments of a selected tissue. As a radiofrequency electrode or microwave antenna, it can be used to ablate or destroy targeted tissues. As a hollow tube, it can be used to deliver a treatment fluid such as a liquid to targeted tissues. The liquid can be a simple solution or a suspension of solids, for example, colloidal particles, in a liquid. Since the stylet is very thin, it can be directed from the catheter through intervening normal tissue with a minimum of trauma to the normal tissue.

[0023] The device of this invention provide a more precise, controlled medical treatment which is suitable for destroying cells of medically targeted tissues throughout the body, both within and external to body organs. The device are particularly useful for treating benign prostate hyperplasia (BPH), and the device and its use are hereinafter described with respect to BPH, for purposes of simplifying the description thereof. It will be readily apparent to a person skilled in the art that the device can be used to destroy body tissues in any body cavities or tissue locations that are accessible by percutaneous or endoscopic catheters, and is not limited to the prostate. Application of the device in all of these organs and tissues are intended to be included within the scope of this invention.

[0024] BPH is a condition which arises from the replication and growth of cells in the prostate and the decrease of cell death rate, forming glandular and stromal nodules which expand the prostate and constrict the opening of the prostatic urethra. Glandular nodules are primarily concentrated within the transition zone, and stromal nodules within the periurethral region. Traditional treatments of this condition have included surgical removal of the entire prostate gland, digital removal of the adenoma, as well as transurethral resection of the urethral canal and prostate to remove tissue and widen the passageway. One significant and serious complication associated with these procedures is iatrogenic sterility. More recently, laser treatment has been employed to remove tissue, limiting bleeding and loss of body fluids. Balloons have also been expanded within the urethra to enlarge its diameter, with and without heat, but have been found to have significant limitations.

[0025] Microwave therapy has been utilized with some success by positioning a microwave antenna within the prostatic urethra and generating heat in the tissue surrounding the urethra with an electromagnetic field. Coolants are sometimes applied within the catheter shaft to reduce the temperature of the urethral wall. This necessitates complicated mechanisms to provide both cooling of the immediately adjacent tissues while generating heat in the more distant prostatic tissue. This technique is similar to microwave hyperthermia. Similarly, radiofrequency tissue ablation with electrodes positioned within the urethra exposes the urethral wall

to destructive temperatures. To avoid this, low temperature settings required to protect the urethra must be so low that the treatment time required to produce any useful effect is unduly extended; e.g. up to three hours of energy application.

[0026] One embodiment of the device of this invention uses the urethra to access the prostate and positions RF electrode stylets directly into the tissues to be destroyed. The portion of the stylet conductor extending from the urethra to targeted tissues is enclosed within a longitudinally adjustable sleeve shield which prevents exposure of the tissue adjacent to the sleeve to the RF current. The sleeve movement is also used to control the amount of energy per unit surface area which is delivered by controlling the amount of electrode exposed. Thus the ablative destruction is confined to the tissues targeted for destruction, namely those causing the constriction. Other aspects of the invention will become apparent from the drawings and accompanying descriptions of the device of this invention. It will be readily apparent to a person skilled in the art that this procedure can be used in many areas of the body for approaches through body orifices.

[0027] Fig. 1 is an isometric view of an RF ablation catheter embodiment of this invention with a fiber optic viewing accessory. The flexible catheter 2, attached to handle 4, has a terminal stylet guide 6 with two stylets 8. The handle has stylet electrode tabs 10 and 11 and sleeve tabs 12 and 13 as will be described in greater detail hereinafter. The handle 4 is also connected to a optical viewing assembly 14 and RF power connector 16, transponder connector 18 and thermocouple connectors 20. The portions of the catheter 2 leading from the handle 4 to the stylet guide tip 6 can optionally has a graduated stiffness. For example, the catheter can be designed to be more stiff near the handle and more flexible near the tip, or any other stiffness profiles. The catheter can be constructed of an inner slotted stainless steel tube with outer flexible sleeve such as is described in U.S. Patent No. 5,322,064. It can also be made of coiled or braided wire to which an outer sleeve is bonded.

[0028] The fiber optic viewing assembly in this embodiment includes a lens focusing assembly 22, a lens viewing assembly support connector 24 assembly attached to a male quick disconnect connector 26 by flexible tubing 28.

[0029] Fig. 2 is a cross-sectional view of a catheter of Fig. 1 showing details of the stylet guide housing. The stylet guide housing 6 has a curved passageway 28 through which the stylet 8 is extended into the tissue to be treated. Further details of these components are described in copending applications Serial No. 08/012,370 filed February 2, 1993, corresponding to WO-A-940220 and WO-A-9417856.

[0030] Fig. 3 is a side view of the stylet and lumen assembly of this invention. The key components of the stylet of this embodiment are an insulating sleeve 30 and an electrode 32 extending therethrough. The electrode 32 has a sharpened tip, in this embodiment a broadened spear tip. The proximal end of the electrode and sleeve are connected by respective sleeve connector 334 and electrode connector 338 to handle sleeve and electrode slides described in greater detail hereinafter with respect to Figs. 10 and 13. An electrode support tube 36 extends from the electrode connector 338 to the area 38 of the sleeve connector 334 to transmit compressive pressure without collapsing the electrode 32. An insulating sleeve support tube 40 made of shrink tubing extends from the sleeve connector 334 to the beginning or proximal end 42 of the outer tubing 44. Tubing 44 joins the support tubing to the control tube 46. The control tube 46 supporting both the electrode and insulating sleeve extends to the junction 48 (see Fig. 4) of the electrode lumen passageway 50 and the electrode 32. In this manner, support is provided over the length of the stylet extending from the handle to the trilumen tip, preventing collapse or loss of linearity of the highly flexible electrode when it is pushed through the stylet guide housing.

[0031] Fig. 4 is a cross-sectional side view of the junction of the stylet and control tube assembly taken along the central axis of the tubing, and Fig. 5 is a cross-sectional view of the junction of the stylet and control tube assembly taken along the line 5-5 of Fig. 4. At the junction 48, the electrode 32 extends through the upper electrode lumen wall 62 and enters the electrode lumen 50. The outer tubing 52 encloses and supports both the distal ends of the control tubing 46 and trilumen sleeve tube 54.

[0032] Referring to Fig. 5, the space 56 between the control tube 46 and the trilumen sleeve tube 54 can be filled with an adhesive to secure them together. The trilumen includes an electrode lumen 50, a temperature sensor lumen 58 and a fluid supply lumen 60 for supply of optional fluids such as antibiotics or anesthetics to the area of treatment.

[0033] Fig. 6 is a cross-sectional view of a trilumen stylet of this invention taken along the line 6-6 in Fig 3. The trilumen sleeve 30 is an insulating sleeve for the electrode 32 and includes the additional temperature sensor lumen 58 and liquid supply lumen 60. The inner surface of the electrode lumen 50 can be spaced from the outer surface of the electrode by a distance "h" which can be, for example, from about 1 to 3 mm to define an additional liquid supply conduit with an approximate annular cross-section.

[0034] Fig. 7 is a cross-sectional side view of the trilumen stylet tip shown in Fig. 6 taken along the line 7-7. The terminal end of the temperature sensor lumen 58 is sealed to protect the electrical components. Thermocouple 64 is placed at the distal end of the sleeve 30 to monitor the temperature of the tissue surrounding the electrode 32 and is preferably less than about 1 mm from the exposed electrode. Thermocouple 66 is placed at least about 3 mm and preferably from about 3 to 6

mm from the tip of sleeve 30 to monitor the temperature of the duct wall (such as the urethra) through which the stylet is extended. This is provided to ensure the duct wall temperature does not reach destructive levels when the RF treatment of tissue surrounding the extended electrode is underway.

[0035] Fig. 8 is a plane view of the annular groove embodiment of the current density focusing electrode of this invention. In this embodiment, the electrode is ground to a single current focusing sharp tip 68 without secondary corner or other sharp edges which could also focus or crowd current. Additional current focusing can be provided along the electrode surface by the annular grooves 70 and 72. The temperature of the tissue surrounding the electrode initially increase in initial zones 74, 76 and 78. The elevated temperature zone then extends to two intermediate zones 80 and 82, as the zones from the grooves merge. Thereafter all of the elevated temperature zones merge to form the single oval zone lesion 84. Use of these current focusing grooves 70 and 72 produces a more symmetrical lesion.

[0036] Fig. 9 is a plane view of the spiral groove embodiment of the current density focusing electrode of this invention. In this embodiment, the electrode is also ground to a single current focusing sharp tip 86 without secondary sharp corners or edges which could also focus or crowd current. Additional current focusing can be provided along the electrode surface by at least one spiral or helical groove 88. The temperature of the tissue surrounding the electrode initially increase in the initial tip zone 90 and a spiral zone 92. The elevated temperature zone then extends to two intermediate zones 94 and 96, as the spiral zone 92 merges to form a single zone 96. Thereafter all of the elevated temperature zones merge to form the single oval zone lesion 98. Use of the spiral focusing groove 88 provides a more symmetrical lesion.

[0037] Fig. 10 is an exploded view of the RF ablation catheter assembly shown in Fig. 1. The upper handle plate 276 has two central slots 278 and 280 through which the electrode control slides 10 and 11 are attached to respective left electrode slide block 282 and right electrode slide block 284. Sleeve control slides 12 and 13 are attached through outer slots 286 and 288 to respective left sleeve slide block 290 and right sleeve slide block 292. Fiber optic receptor housing 30 is mounted on the proximal surface of the upper handle plate 276. The electrical receptor 294 is received in respective cavities 296 and 298 in the upper handle plate 276 and lower handle plate 300 attached thereto. The lower handle plate 300 has a central cavity 302 which accommodates the electrode and sleeve slide blocks and associated elements.

[0038] Microswitch activator blocks 304 (only left sleeve block shown) are connected to the sleeve slide blocks 290 and 292. They are positioned to actuate the microswitches 306 when the respective sleeve block (and sleeve attached thereto) have been advanced. The microswitches 306 hold the respective RF power circuits open until the respective sleeves are advanced to a position beyond the urethra wall and into the prostate to prevent direct exposure of the urethra to the energized RF electrodes. Extension of the sleeve 5 mm beyond the guide is usually sufficient to protect the urethra.

[0039] The tension-torque tube assembly 308 is mounted in the distal end of the housing in the receptor 310.

[0040] Fig. 11 is an isometric view of the adjuster block and tension tube assembly 308 of the RF ablation catheter shown in Fig. 10. The torque tube 312 extends from the torque coupler 314 through the twist control knob 316 to the stylet guide 6. Bending flexure of the torque tube 312 during use lengthens the path from the handle to the guide tip 6. To prevent a resulting retraction of the stylet sleeve and electrode components when the torque tube 312 is flexed, a tension tube 318 having a fixed length and diameter smaller than the inner diameter of the torque tube 312 is provided. The distal end of the tension tube 318 is securely attached to the stylet guide 6, and the proximal end 320 is secured to the adjuster block 322, for example by an adhesive. The axial position of the adjuster block 322 can be adjusted to ensure the stylets 8 are initially positioned just inside the outlet ports in the stylet guide 6. Torque coupler 314 is mounted on the coupler block 324. Twist control knob stop pin 326 extends into a grove (not shown) and limits rotation of the control knob 316.

[0041] Fig. 12 is a detailed view "A" of the distal end tension tube connections of the tension tube shown in Fig. 11. The tension tube 318 is securely connected to the proximal end 328 of the stylet guide 6, for example by a length of shrink tubing 330.

[0042] Fig. 13 is an exploded view of the sleeve and electrode slide block assembly of the embodiment shown in Fig. 10. The right sleeve slide block 292 has a projection 332 which extends inward under the right electrode slide block 284. Right sleeve connector 334 is mounted to the inner end of the projection 332, secured to the end of the proximal end of the sleeve 336. Right electrode connector 338 is attached to an inner surface of the electrode slide block 284 and is secured to the proximal end of electrode 340. The right sleeve and electrode slide blocks 292 and 284 are slidingly attached to the right friction adjustment rail 342 by screws (not shown) through slots 348 and 346, the screws being adjustable to provide sufficient friction between the blocks and the rail 342 to provide secure control over the stylet movement. The left sleeve slide block 290 and left electrode slide block 282 are mirror replicas of the right blocks and are similarly mounted on the left friction rail 344. The left sleeve and electrodes are not shown.

Claims

1. A medical probe device for medical treatment of tissue at a treatment site in a body accessible through a natural body lumen defined by a wall and opening outside the body to provide a natural body opening comprising a catheter (2) having proximal and distal extremities and having a passageway (28) extending from the proximal extremity to the distal extremity, a flexible stylet (8) slidably mounted in the passageway, the distal extremity of the catheter having a stylet guide housing (6) having at least one stylet port and stylet guide means in communication with the passageway for directing the stylet sidewise of the catheter, the stylet including an insulating sleeve (30) having proximal and distal extremities and having an electrode lumen (50) terminating in a distal port at the distal extremity of the insulating sleeve, a radio frequency electrode (32) being positioned in the electrode lumen for longitudinal movement therein, a handle (4) coupled to the proximal extremity of the catheter for introducing the distal extremity of the catheter into the natural body opening to a position adjacent the treatment site, the handle including means (334,338,10,11,12,13) for advancing the stylet to cause the tip of the radio frequency electrode to penetrate the wall and extend into the tissue at the treatment site with the insulating sleeve extending through the wall, means (16) for supplying radio frequency energy to the radio frequency electrode to cause a thermal effect in the tissue at the treatment site while the insulating sleeve protects the wall from the thermal effect caused by the radio frequency energy, the insulating sleeve being provided with a second lumen (60) extending from the proximal extremity to the distal extremity of the insulating sleeve.

2. A medical probe device as in Claim 1 wherein a third lumen (58) is provided in the insulating sleeve that terminates in a sealed closure adjacent the distal end of the insulating sleeve and in which lumen a temperature sensing means (64) is provided which is positioned at the distal extremity of the insulating sleeve.

3. A medical probe device as in Claim 2 wherein an additional temperature sensing means (66) is disposed in the second lumen (60) of the insulating sleeve (30), the additional temperature sensing means (66) being spaced proximally from said first temperature sensing means (64) whereby, when the insulating sleeve is disposed in the wall, said first temperature sensing means monitors the temperature of the tissue surrounding the radio frequency electrode (32) and the additional temperature sensing means monitors the temperature of the wall.

4. A device as in Claim 2 wherein the inner surface of the electrode lumen is spaced from the outer surface of the radio frequency electrode (32) to define an additional liquid supply duct with an approximate annular cross section.

5. A medical device as in Claim 2 wherein the insulating sleeve (30) is provided with a third lumen (58) extending from the proximal extremity to the distal extremity of the insulating sleeve spaced apart from the second lumen (60).

6. A medical probe device as in Claim 1 wherein means (334,338,10,11,12,13) is carried by the handle (4) for causing relative movement between the insulating sleeve and the radio frequency electrode.

7. A medical probe device as in Claim 1 wherein the radio frequency electrode (32) has a distal length provided with at least one current focusing groove (70) thereon, the tip (68) being shaped to focus current on its terminal end whereby radio frequency current passing therefrom into surrounding tissue forms a lesion extending outward from the groove and tip.

8. A medical probe device as in Claim 7 wherein the distal length of the radio frequency electrode (32) is provided with a plurality of annular focusing grooves (70,72) thereon.

9. A medical probe device as in Claim 7 wherein the distal length of the radio frequency electrode (32) is provided with a spiral focusing groove (88) thereon.

Patentansprüche

1. Medizinische Sondenvorrichtung zur medizinischen Behandlung von Gewebe an einer Behandlungsstelle in einem Körper, die über ein natürliches Körperlumen zugänglich ist, das durch eine Wand definiert ist und sich in Bezug auf den Körper nach außen öffnet, wodurch eine natürliche Körperöffnung entsteht, umfassend einen Katheter (2) mit einem proximalen und einem distalen Ende, der einen Durchgang (28) aufweist, der sich vom proximalen Ende zum distalen Ende erstreckt, einen flexiblen Katheterdrain (8), der so im Durchgang montiert ist, dass er darin gleiten kann, wobei das distale Ende des Katheters ein Katheterdrain-Führungsgehäuse (6) aufweist, das zumindest eine Katheterdrain-Öffnung und ein Katheterdrain-Führungsmittel aufweist, das sich mit dem Durchgang in Kommunikation befindet, um den Katheterdrain in Bezug auf den Katheter zur Seite zu lenken, wobei der Katheterdrain eine Isolierhülle (30)

umfasst, die ein proximales und ein distales Ende aufweist sowie ein Elektrodenlumen (50) aufweist, das in einer distalen Öffnung am distalen Ende der Isolierhülle endet, wobei eine Radiofrequenzelektrode (32) so in, Elektrodenlumen angeordnet ist, dass sie sich in Längsrichtung darin bewegen kann, einen Griff (4), der an das proximale Ende des Katheters gekoppelt ist, um das distale Ende des Katheters bis zu einer Position in die natürliche Körperöffnung einzuführen, die an die Behandlungsstelle angrenzt, wobei der Griff Mittel (334, 338, 10, 11, 12, 13) umfasst, um den Katheterdrain vorwärts zu bewegen, um zu bewirken, dass die Spitze der Radiofrequenzelektrode die Wand durchdringt und sich an der Behandlungsstelle in das Gewebe erstreckt, wobei sich die Isolierhülle durch die Wand erstreckt, Mittel (16) zum Zuführen von Radiofrequenzenergie zur Radiofrequenzelektrode, um im Gewebe an der Behandlungsstelle eine thermische Wirkung zu verursachen, während die Isolierhülle die Wand vor der thermischen Wirkung schützt, die durch die Radiofrequenzenergie verursacht wird, wobei die Isolierhülle mit einem zweiten Lumen (60) versehen ist, das sich vom proximalen Ende zum distalen Ende der Isolierhülle erstreckt.

2. Medizinische Sondenvorrichtung nach Anspruch 1, worin in der Isolierhülle ein drittes Lumen (58) vorgesehen ist, das in einem abgedichteten Verschluß in Nachbarschaft des distalen Endes der Isolierhülle endet und in dem ein Temperaturfühlermittel (64) vorgesehen ist, das am distalen Ende der Isolierhülle angeordnet ist.

3. Medizinische Sondenvorrichtung nach Anspruch 2, worin ein zusätzliches Temperaturfühlermittel (66) im zweiten Lumen (60) der Isolierhülle (30) angeordnet ist, wobei das zusätzliche Temperaturfühlermittel (66) proximal vom erstgenannten Temperaturfühlermittel (64) beabstandet ist, wodurch, wenn die Isolierhülle in der Wand angeordnet ist, das erstgenannte Temperaturfühlermittel die Temperatur des die Radiofrequenzelektrode (32) umgebenden Gewebes überwacht und das zusätzliche Temperaturfühlermittel die Temperatur der Wand überwacht.

4. Vorrichtung nach Anspruch 2, worin die Innenfläche des Elektrodenlumens von der Außenfläche der Radiofrequenzelektrode (32) beabstandet ist, so dass eine zusätzliche Flüssigkeitszufuhrleitung definiert wird, die einen in etwa ringförmigen Querschnitt aufweist.

5. Medizinische Vorrichtung nach Anspruch 1, worin die Isolierhülle (30) mit einem dritten Lumen (58) versehen ist, das sich in einem Abstand vom zweiten Lumen (60) vom proximalen Ende zum distalen Ende der Isolierhülle erstreckt.

6. Medizinische Sondenvorrichtung nach Anspruch 1, worin ein Mittel (334, 338, 10, 11, 12, 13) vom Griff (4) getragen wird, um Relativbewegung zwischen der Isolierhülle und der Radiofrequenzelektrode zu bewirken.

7. Medizinische Sondenvorrichtung nach Anspruch 1, worin die Radiofrequenzelektrode (32) eine distale Länge aufweist, die mit zumindest einer Stromfokussierungsrille (70) darauf versehen ist, wobei die Spitze (68) so geformt ist, dass sie Strom auf ihrem Endpunkt fokussiert, wodurch Radiofrequenzstrom, der daraus in das umgebende Gewebe gelangt, eine Läsion bildet, die sich von der Rille und Spitze nach außen erstreckt.

8. Medizinische Sondenvorrichtung nach Anspruch 7, worin die distale Länge der Radiofrequenzelektrode (32) mit einer Vielzahl ringförmiger Fokussierungsrillen (70, 72) darauf versehen ist.

9. Medizinische Sondenvorrichtung nach Anspruch 7, worin die distale Länge der Radiofrequenzelektrode (32) mit einer spiralförmigen Fokussierungsrille (88) darauf versehen ist.

Revendications

1. Dispositif à sonde médicale pour le traitement médical de tissus à un site de traitement dans un corps accessible à travers une lumière naturelle du corps définie par une paroi et une ouverture à l'extérieur du corps afin de procurer une ouverture naturelle du corps, comprenant un cathéter (2) ayant des extrémités proximale et distale et ayant un passage (28) s'étendant de l'extrémité proximale à l'extrémité distale, un stylet flexible (8) monté de manière permettant le coulissement dans le passage, l'extrémité distale du cathéter ayant un logement de guidage du stylet (6) comportant au moins une porte de stylet et un moyen de guidage de stylet en communication avec le passage pour diriger le stylet sur le côté du cathéter, le stylet incluant un manchon d'isolation (30) ayant des extrémités proximale et distale et ayant une lumière d'électrode (50) se terminant par une porte distale à l'extrémité distale du manchon d'isolation, une électrode de radiofréquence (32) étant positionnée dans la lumière d'électrode pour effectuer un mouvement longitudinal dans celle-ci, une poignée (4) couplée à l'extrémité proximale du cathéter pour introduire l'extrémité distale du cathéter dans l'ouverture naturelle du corps vers une position adjacente au site de traitement, la poignée comprenant des moyens (334, 338, 10, 11, 12, 13) pour

faire avancer le stylet de façon à amener l'extrémité de l'électrode de radiofréquence à pénétrer dans la paroi et s'étendre dans le tissu au site de traitement, le manchon d'isolation s'étendant à travers la paroi, des moyens (16) pour apporter de l'énergie de radiofréquence à l'électrode de radiofréquence afin de provoquer un effet thermique dans le tissu au site de traitement tandis que le manchon d'isolation protège la paroi de l'effet thermique provoqué par l'énergie de radiofréquence, le manchon d'isolation étant pourvu d'une deuxième lumière (60) s'étendant de l'extrémité proximale à l'extrémité distale du manchon d'isolation.

2. Dispositif à sonde médicale suivant la revendication 1, dans lequel une troisième lumière (58) est prévue dans le manchon d'isolation et se termine par une fermeture scellée adjacente à l'extrémité distale du manchon d'isolation et dans laquelle lumière un moyen de détection de la température (64) est prévu, lequel est positionné à l'extrémité distale du manchon d'isolation.

3. Dispositif à sonde médicale suivant la revendication 2, dans lequel un moyen supplémentaire de détection de la température (66) est disposé dans la deuxième lumière (60) du manchon d'isolation (30), le moyen supplémentaire de détection de la température (66) étant espacé de manière proximale du premier moyen mentionné de détection de la température (64), le premier moyen mentionné de détection de la température surveillant la température du tissu entourant l'électrode de radiofréquence (32) et le moyen supplémentaire de détection de la température surveillant la température de la paroi lorsque le manchon d'isolation est disposé dans la paroi.

4. Dispositif suivant la revendication 2, dans lequel la surface intérieure de la lumière d'électrode est espacée de la surface extérieure de l'électrode de radiofréquence (32) afin de définir un conduit supplémentaire d'apport de liquide avec une section transversale approximativement annulaire.

5. Dispositif médical suivant la revendication 1, dans lequel le manchon d'isolation (30) est pourvu d'une troisième lumière (58) s'étendant de l'extrémité proximale à l'extrémité distale du manchon d'isolation en étant espacée de la deuxième lumière (60).

6. Dispositif à sonde médicale suivant la revendication 1, dans lequel des moyens (334, 338, 10, 11, 12, 13) sont portés par la poignée (4) pour provoquer un mouvement relatif entre le manchon d'isolation et l'électrode de radiofréquence.

7. Dispositif à sonde médicale suivant la revendication 1, dans lequel l'électrode de radiofréquence (32) a une longueur distale pourvue sur celle-ci d'au moins une rainure de focalisation du courant (70), l'extrémité (68) étant formée de façon à focaliser le courant à son extrémité terminale, le courant de radiofréquence passant de celle-ci dans les tissus environnant formant une lésion s'étendant à l'extérieur de la rainure et de l'extrémité.

8. Dispositif à sonde médicale suivant la revendication 7, dans lequel la longueur distale de l'électrode de radiofréquence (32) est pourvue sur celle-ci d'une pluralité de rainures de focalisation annulaires (70, 72).

9. Dispositif à sonde médicale suivant la revendication 7, dans lequel la longueur distale de l'électrode de radiofréquence (32) est pourvue sur celle-ci d'une rainure de focalisation spiralée (88).

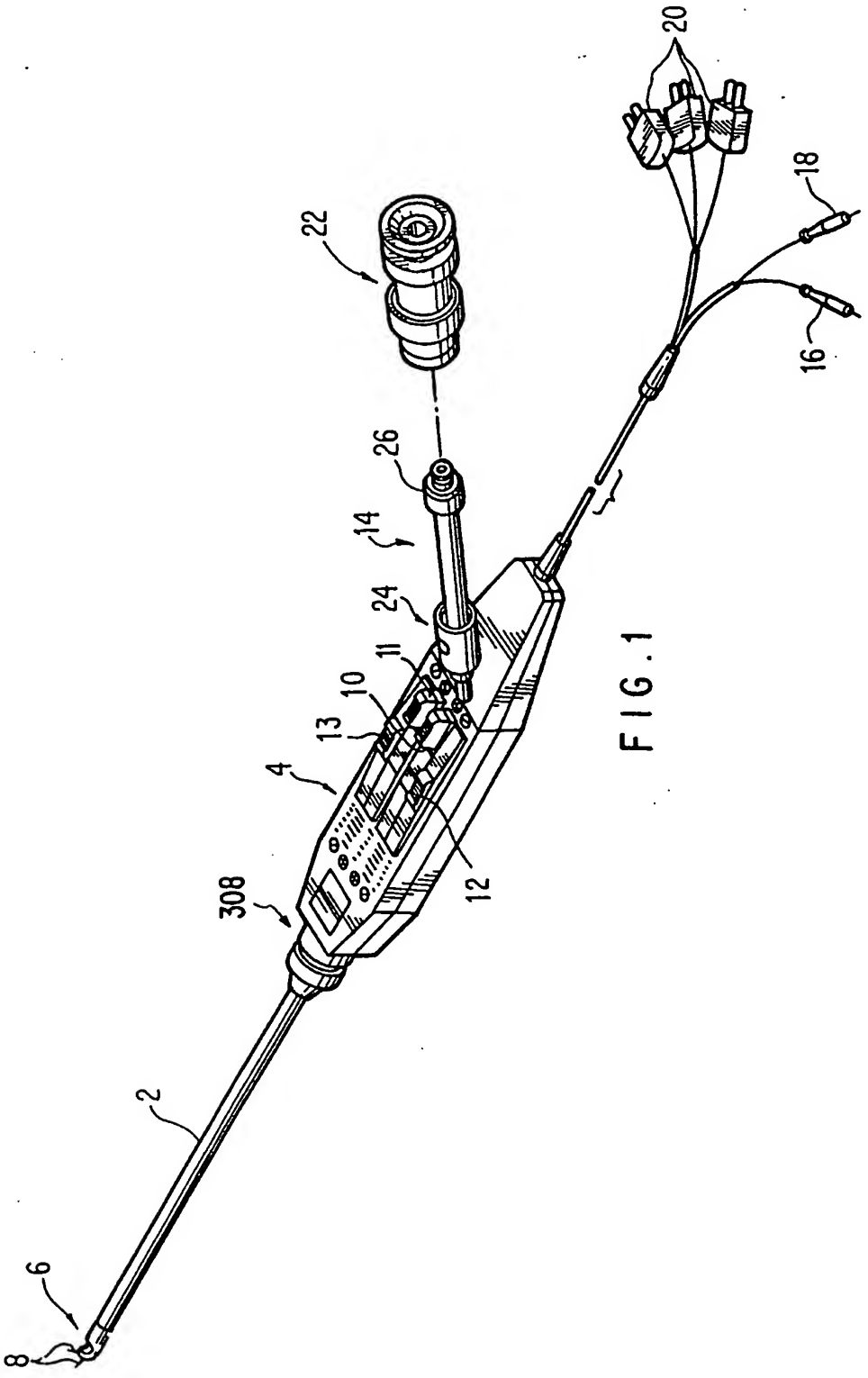


FIG.1

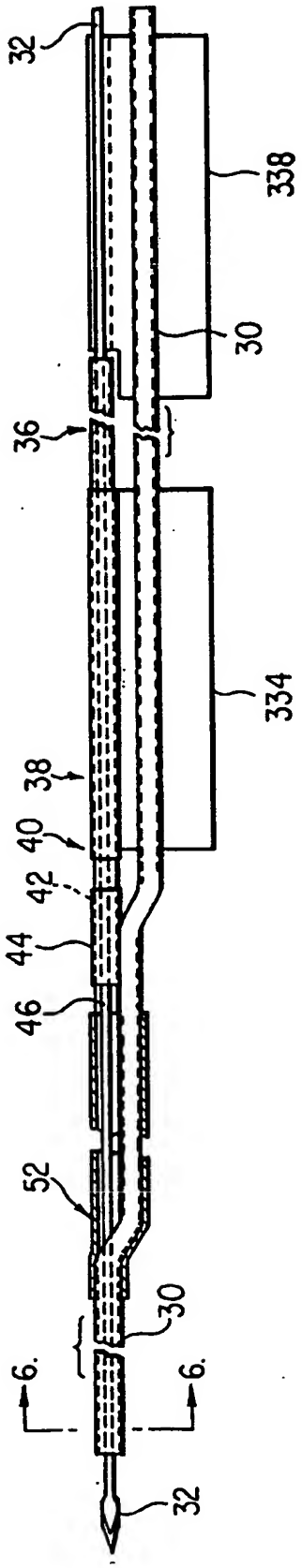


FIG. 3

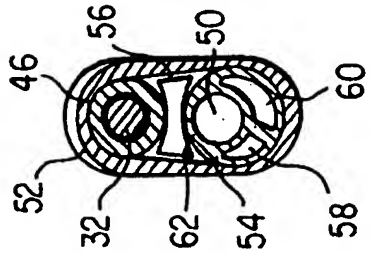


FIG. 5

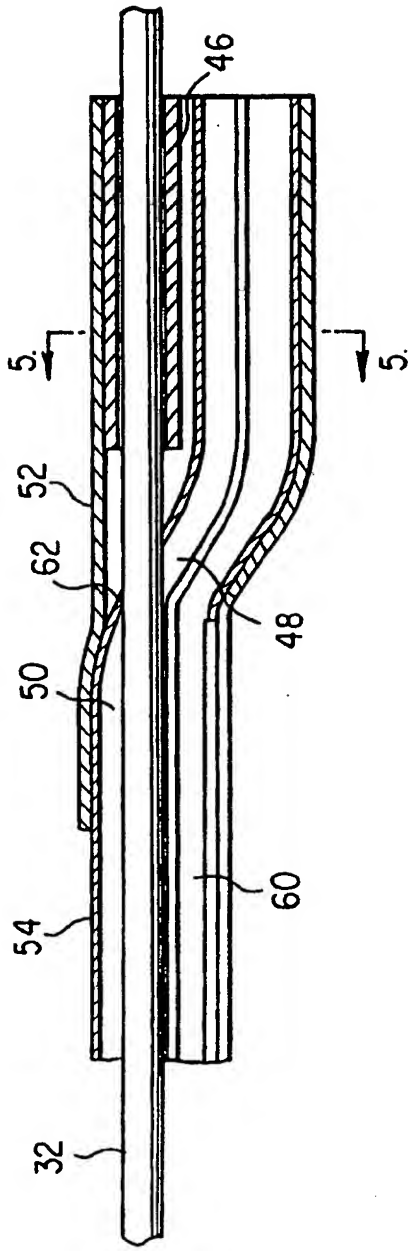


FIG. 4

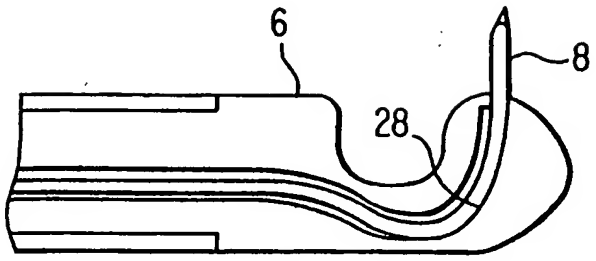


FIG. 2

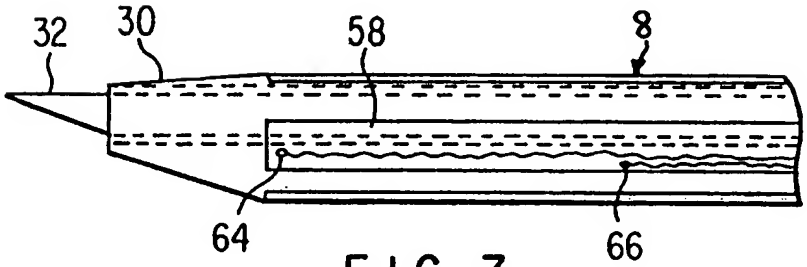


FIG. 7

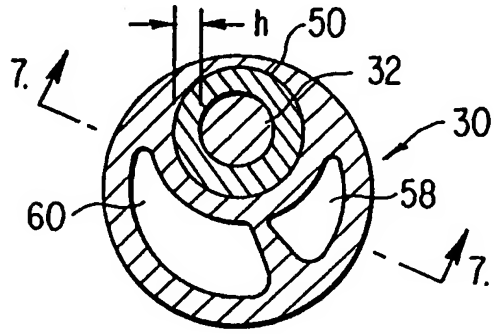


FIG. 6

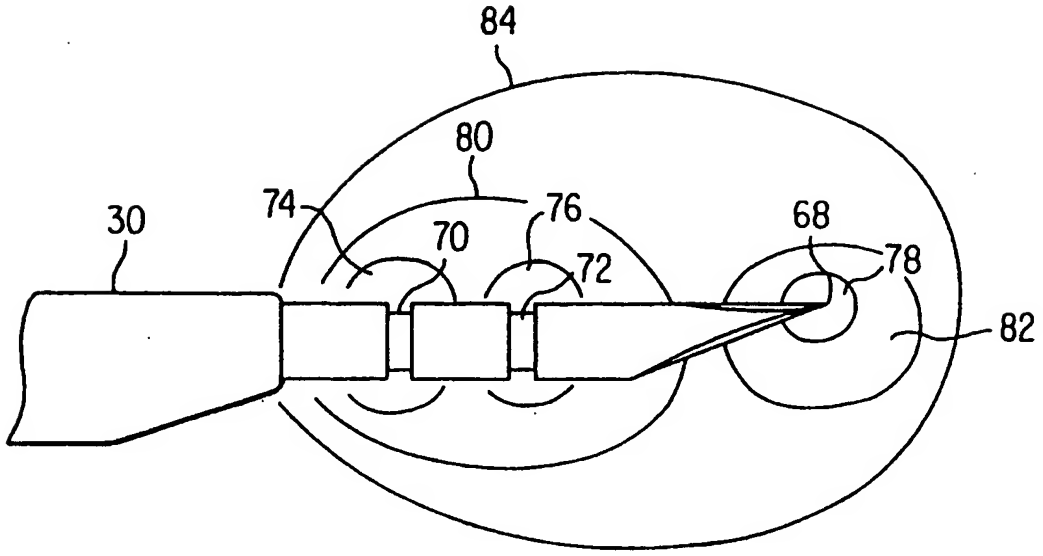


FIG. 8

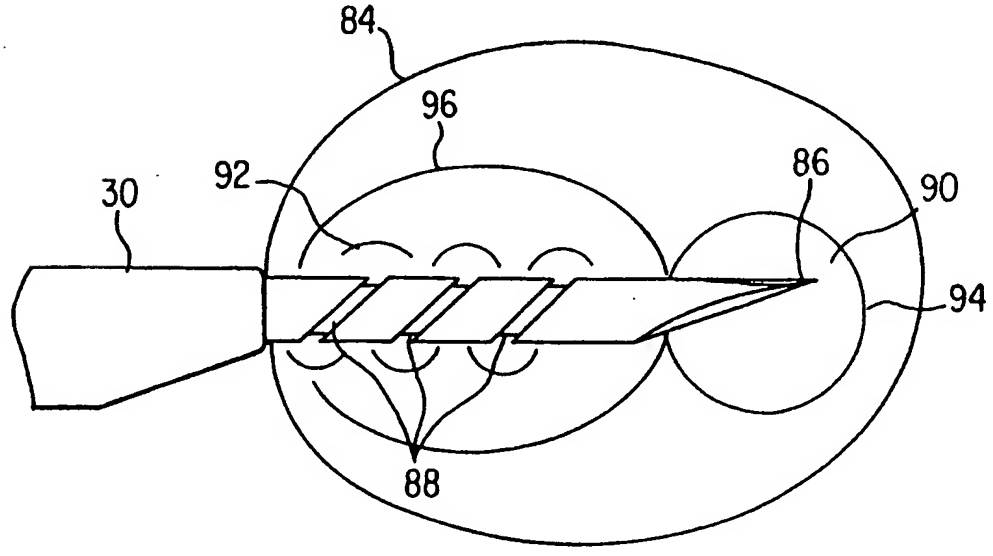


FIG. 9

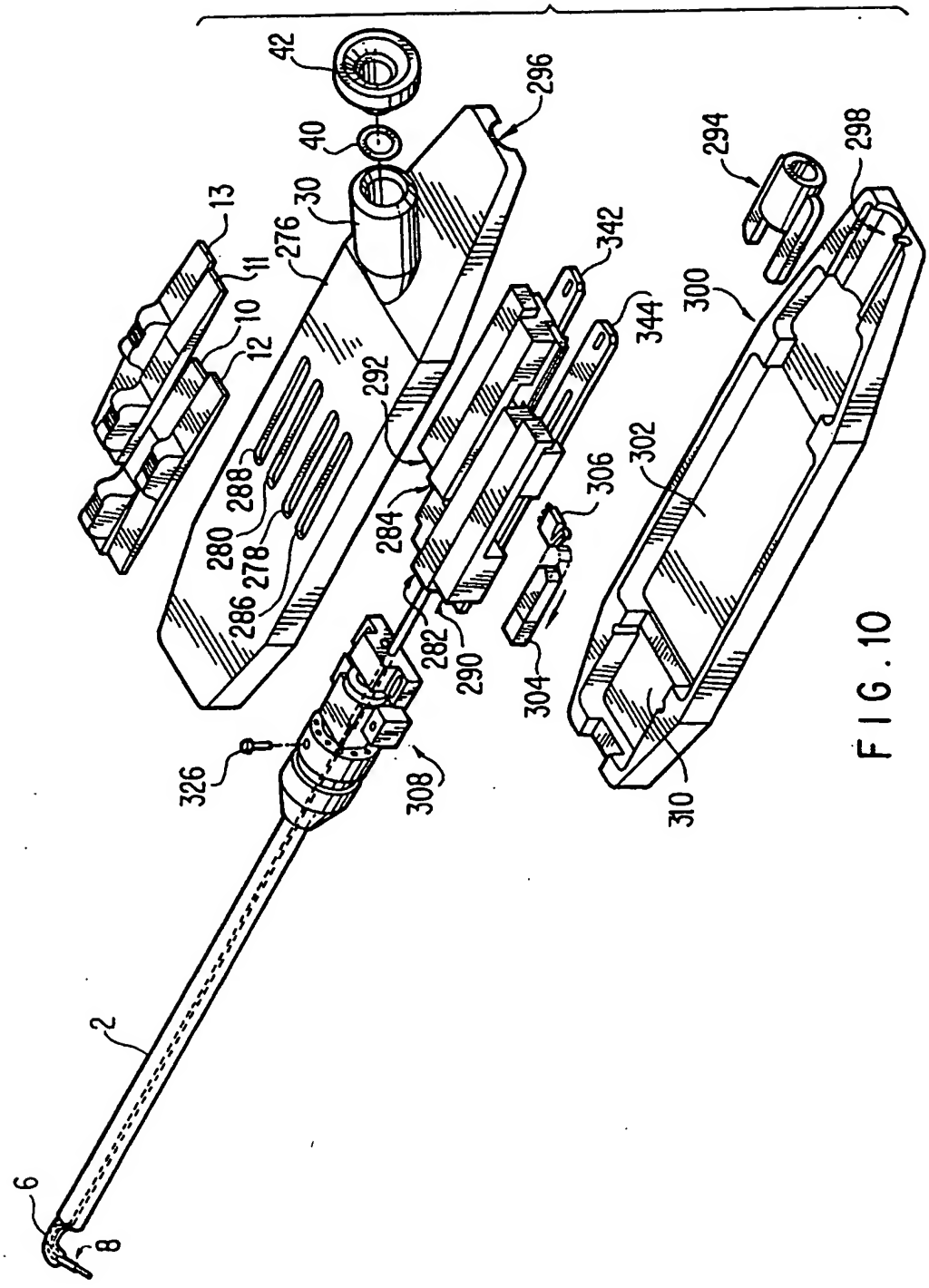

42
40
296
30
276
13
11
10
12
292
288
280
278
286
284
342
344
300
294
298
306
302
282
290
304
310
326
308
2
6
8

FIG. 10

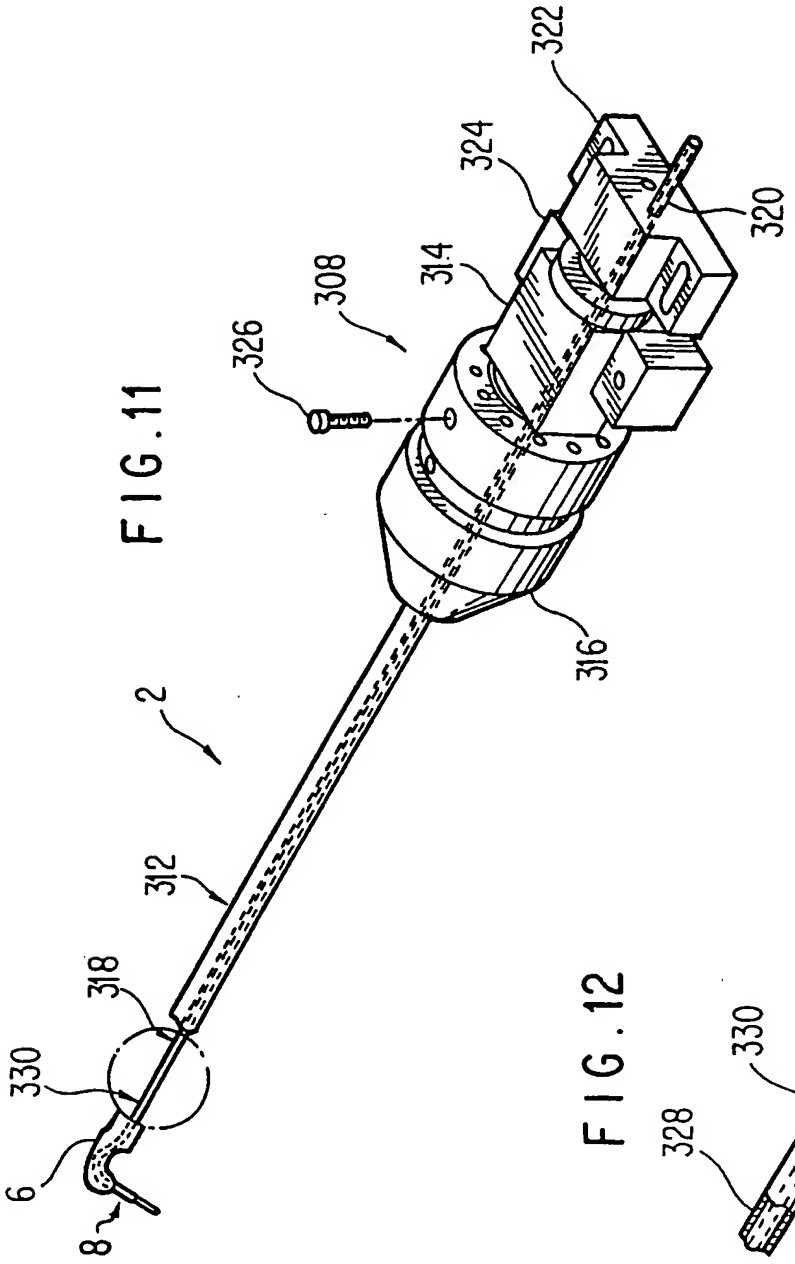


FIG.11

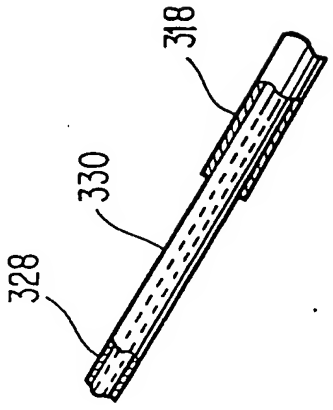
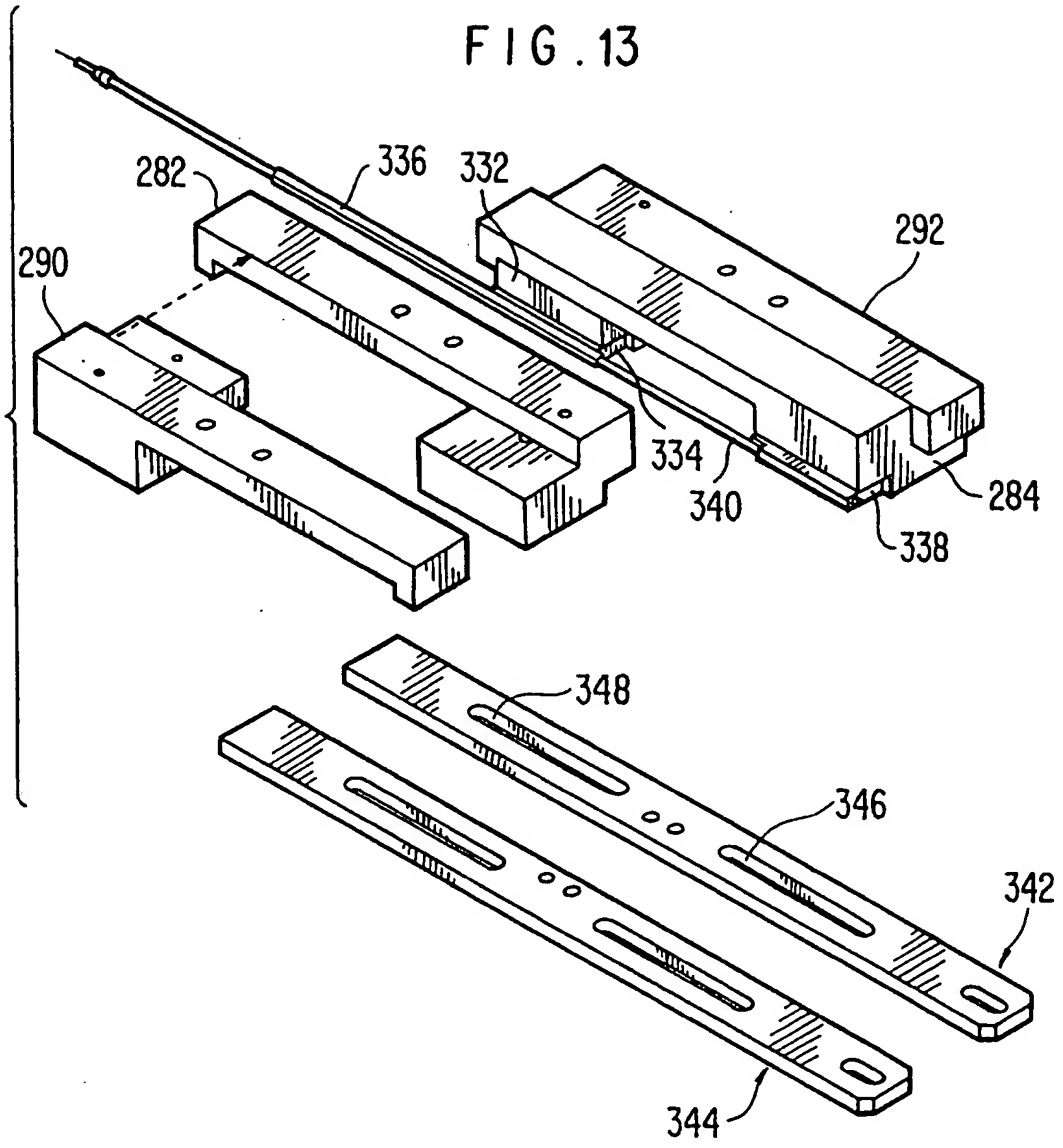


FIG.12

FIG. 13



BE

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 831 751 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
06.11.2002 Bulletin 2002/45

(21) Application number: **96917215.4**

(22) Date of filing: **06.06.1996**

(51) Int Cl.[7]: **A61F 2/00**

(86) International application number:
PCT/US96/09032

(87) International publication number:
WO 96/039991 (19.12.1996 Gazette 1996/55)

(54) **URETHRAL CAP**

HARNRÖHRENKAPPE

CAPUCHON URETRAL

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **07.06.1995 US 476092**
02.11.1995 US 556766

(43) Date of publication of application:
01.04.1998 Bulletin 1998/14

(73) Proprietor: **Nebl,Inc.**
Worcester, MA 01609 (US)

(72) Inventors:
- **BOGOJAVLENSKY, Sergei**
Harvard, MA 01451 (US)
- **SCHAEFER, Robert, W.**
Boston, MA 01740 (US)
- **SCHLESINGER, Robert**
Dedham, MA 02026 (US)

(74) Representative: **Pratt, David Martin et al**
Withers & Rogers,
Goldings House,
2 Hays Lane
London SE1 2HW (GB)

(56) References cited:
WO-A-90/08561
FR-A- 1 223 353
GB-A- 2 193 438
DE-A- 3 633 824
GB-A- 1 467 144
US-A- 3 958 564

EP 0 831 751 B1

Printed by Jouve, 75001 PARIS (FR)

Description

Background of the Invention

[0001] Urinary incontinence, such as stress incontinence, in females is a substantial problem throughout the world. A variety of mechanisms have been suggested for use to alleviate the condition, which can be a social as well as a medical problem, to those afflicted with the problem.

[0002] Many suggested medical devices to alleviate urinary incontinence in females require the use of internal components, such as catheters, balloons, pessaries or the like, which pass into the urethra, and are positioned within the body in use. Such internal components can be a source of irritation to the body and, in some cases, can result in infection or other unwanted body reactions. Moreover, such devices as are known can be expensive and/or inconvenient to use and transport for use.

[0003] GB-A-2193438 describes a urethral cap comprising a resilient, and at least partially-deformable, body defining a chamber therewithin, as well as an encircling flange having a body-contacting surface which acts as a sealing surface.

Summary of the Invention

[0004] It is an aim of this invention to provide a urethral cap for alleviating urinary incontinence, such as stress incontinence in females, which cap is inexpensive to provide, is simple to apply and remove, and which does not create a high risk of body infection.

[0005] Another aim of this invention is to provide a urethral cap in accordance with the preceding cap which utilises atmospheric pressure to maintain the cap in position on the body of a user.

[0006] Still another aim of the present invention is to provide a urethral cap in accordance with the preceding objects which can incorporate a sealing material which can be a lubricant or adhesive to aid attachment to the body.

[0007] Still another aim of the present invention is to provide a urethral cap usable in a method of alleviating urinary incontinency in a user by applying this urethral cap blocking the outer orifice of the urethra at the meatus, and utilising an air pressure difference to maintain the cap on the body of a user.

[0008] Still another aim of this invention is to provide a urethral cap usable in a method in accordance with the preceding method, wherein an adhesive is used in conjunction with holding the cap on the body.

[0009] Still another aim of this invention is to provide a urethral cap usable in a method in accordance with the preceding aims which can be rapidly carried out by a user, and provides safe and certain protection against incontinency in women.

[0010] The present invention provides a urethral cap for alleviating urinary incontinence when applied over the meatus of the body of a user, the cap comprising a resilient, at least partially-deformable cap body having a hand gripping portion, the cap body defining a chamber therewithin sized to allow for reciprocal resilient deformation of the cap body to provide a vacuum therein to hold the urethral cap on the body of the user, and to close the meatus of the body of the user, the chamber defining a central axis passing from the top of the cap to the bottom of the cap, the cap body defining, at its bottom, an encircling flange having a body-contacting surface to act as a sealing surface with the body of the user, thereby closing the meatus of the user by compression, wherein the cap carries a sealing material over the body-contacting surface for aiding in preventing liquid flow between the body-contacting surface and the body of the user when the cap is in use, characterised in that the cap provides a generally frustoconical inner surface adjacent to the body-contacting surface to aid in closing the meatus by compression.

[0011] Preferably, the encircling flange has a diameter of substantially 3 centimetres, and preferably in the range of substantially 2.4 to 3.3 centimetres, to allow proper positioning on the female body at the orifice of the urethra. Preferably, the cap is formed of a resilient body-compatible rubbery material such as silicone rubber, and can be sterilised and packaged under sterile conditions.

[0012] By using the invention, urinary incontinence in women is alleviated and unwanted urinary flow prevented by applying a urethral cap having an internal chamber, over a urethra outer body orifice of the user. The cap defines a hand-gripping portion and an encircling flange having a body-contacting surface which aids in sealing the urethral cap to the body of the user. Air pressure is employed below atmospheric air pressure to maintain the cap in place, and to compress the meatus. The urethral cap is removed to allow voiding when desired, and can be re-applied.

[0013] It is a feature of this invention that the chance of infection and internal irritation to a user is reduced, since no components of the cap pass into, or through, the urethra of the user, and the cap is external to the body. The cap can be made of standard non-irritating body-compatible materials such as silicone rubbers and the like. In use, the air pressure difference between the chamber of the cap and the atmosphere holds the cap in place. This positioning can be enhanced by use of an adhesive sealing material if desired, and/or is preferably enhanced by the use of a non-adhesive sealing material. The sealing material can be pre-applied. The cap allows for collection of a small amount of urine in an internal chamber, as well as ease of removal to allow urinary flow and ease of replacement. In ordinary use, the meatus is closed by the urethral cap, and no urine leakage occurs to the chamber or outside of the body. The cap can be made relatively inexpensively of inexpensive materials in proper sizing as required. A small number

of sizes can be used to fit the vast majority of users.

Brief Description of the Drawings

[0014] The above and other objects, features and advantages of the present invention will be better understood from the following description when read in conjunction with the accompanying drawings, in which:

FIG. 1 is a top view of a preferred embodiment of the urethral cap in accordance with this invention;
FIG. 2 is a cross-sectional view thereof taken through line 2-2 Of FIG. 1;
FIG. 3 is a bottom view thereof;
FIG. 4 is a cross-sectional view through a section of the flange of a cap in accordance with FIG. 1 having a plurality of sealing layers applied thereto;
FIG. 5 is a semi-diagrammatic top plan view of the urethral cap of FIG. 1 in place on the body of the user; and
FIG. 6 is a diagrammatic cross-sectional view as through line 2-2 of FIG. 1 of the urethral cap when in place on the body of the user.

Detailed Description

[0015] A preferred embodiment of a urethral cap or incontinence device is illustrated at 10 as best shown in FIGS. 1-3. The cap comprises a body 11 defining an inner chamber 12 with an outer flange 13 and an intermediate frustoconical portion 14.

[0016] The body of the urethral cap in the preferred embodiment of FIG. 1 has a cylindrical wall 15 around a central axis 40 of the cap, with a rounded outer end wall 16, a finger gripping ledge 17 and a body contacting encircling surface 18 are provided.

[0017] The urethral cap is preferably integrally formed as by conventional molding but can be made by dipping, spraying or other techniques. The material of the integral cap is preferably an FDA approved medical grade silicone rubber. However, elastomeric materials such as medical grade silicone rubber sold by Dow Corning Co., elastomeric urethanes, polyvinyl chlorides, natural and other rubbery material or synthetic polymeric materials can be used. In some cases, the body need not be integrally formed but can be formed of rigid materials which can be polymeric or metallic. In these cases, at least a portion of the body opening into the interior chamber 12 is formed of a resilient material which can be elastically and reciprocally moved by the fingers from the at rest position as shown in FIG. 2 to a compressed or reduced chamber position and then allowed to expand to the at rest position. This is necessary in order to provide at least a partial vacuum in the chamber to seal the cap to the body by an air pressure differential between the air within the chamber and the atmospheric air pressure as will be described.

[0018] The side wall thickness of the cap is arranged so that side wall 15 has a thicker section and is more resistant to collapse or deformation by atmospheric pressure than is the flange portion 13 which tapers from the wall 15. The thickness of wall 15 can be, for example, 1.75 millimeter thick with a preferred range of 1.5 to 2.5 millimeter, with a flange 13 thickness I of, for example, 0.75 millimeter in the preferred embodiment and a preferred range of 0.5 to 1.5 millimeter and can be formed of an FDA approved medical grade silicone rubber. This difference in wall thickness prevents collapse on itself of the device in use, yet, allows for movement of the flange towards the body in use.

[0019] As best seen in the cross section of FIG. 6, the flange 13 can be deformed towards or closely contact the body at the planar area of the body surrounding the meatus or urethra orifice. A portion of orifice of the urethra indicated at 20 can be drawn into contact with the flange 13 and the frustoconical portion 14 which acts to close the meatus in order to maintain position of the cap, to form a good seal with the body at flange 13 and to close the meatus to urine flow.

[0020] In use, the meatus is preferably closed by a gentle compression of the area around the meatus to form a closure maintained in position by an air pressure difference. Any structure that provides a closure of the meatus to urine flow, yet allows comfort in use and ease of reuse, can provide the advantages of this invention. These advantages can be obtained by the device 10 acting solely externally of the body without any part thereof entering the body of a user.

[0021] The end wall 16 of the cap preferably provides a hand gripping wall 17 although any configuration which allows for finger gripping of the cap to allow positioning on the body and removal therefrom by the fingers of the user is acceptable. Thus, although the cap is shown as a cylindrical side wall, rounded end wall top with frustoconical section 14 and encircling flange 13, the shape can vary greatly. The section 14 is important to provide the closure of the meatus. Generally, the angle of the interim wall surface 141 with the surface 18 is obtuse to enhance closure of the meatus. This internal wall surface 141 is a lower portion of chamber 12 and closes the meatus by pressure thereof.

[0022] It is preferred that the flange 13 provide a body contacting surface 18 forming a continuous ring about the opening or meatus of the urethra of the body. However, other portions of the cap can be square, round, oblong, bulbous, or of any shape desired. Flat, rather than rounded end wall 16 can be used. In all cases, sufficient interior space is provided at the inner chamber 12 which extends to the tip of the flange, to provide for forming an at least partial vacuum in the chamber by finger compression, and allowing resilient rebound to the positioning as in FIG. 6.

[0023] The dimensions of the urethral cap can vary greatly.

[0024] However, consistent with normal anatomy of females in the United States, it is preferred that the di-

ameter A be in the range of 2.3 to 3.4 centimeters and more preferably 2.4 to 3.3 centimeters with 3 centimeters being used in the preferred embodiment. Where the flange 13 is oval or of other encircling shapes such as square, oblong, triangular or the like, the maximum flange width corresponding to the diameter of flange 13 between the labia is about 3.4 centimeters. Diameter B is preferably in the range of 1 centimeter to 2.5 centimeters with 1.5 millimeters being preferred. The height D of the device is preferably 1 to 3 centimeters and in the preferred embodiment 2 centimeters. This height can vary greatly but by maintaining the device approximately 1 to 3 centimeters in height, the device can be worn without discomfort, positioned easily and is resistant to dislodging by garments worn by the user.

[0025] Distance E can be, for example, 1.35 centimeters in the preferred embodiment with the chamber diameter of chamber I2 shown at F being 75 millimeters in the preferred embodiment. Distance H which defines in part the interior chamber can be 5.25 millimeters in the preferred embodiment but again can vary greatly. The most important dimensions relate to the range of 2.3 to 3.4 centimeters in outer diameter of flange 13 for proper positioning in the body and preferably the height is no more than about 3 centimeters to allow ease of use and 'reuse.

[0026] In the preferred embodiment, Silastic HS-30, manufactured by Dow-Corning Corp. of Midland, Michigan, is used as the elastomeric material for the integral cap 10. The Silastic HS-30 preferably has a Durometer Shore A of 32, tensile strength psi (Mpa) 1325(9.13) and an elongation of 1020%. The Silastic silicone rubber can be cured with conventional peroxide curing agents such as Lupersol 101, a product of Penwalt Corp. of Buffalo, New York. Conventional colorants can be used to add color as, for example, organic and inorganic pigments.

[0027] In use, a sealant material which can be an adhesive but need not be an adhesive, is applied to the body contacting surface 18. The purpose of this material shown in FIG. 4 at 30 is to provide an air and liquid seal between the skin of the body and the flange. If the seal is adhesive, it not only seals against air and liquid pressure leakage, but can also act to hold the device in contact with the body. However, it is preferred not to use solely an adhesive as the body adhering portion since this could be irritating to the body if sufficient adhesive is used to provide proper protection. On the other hand, when substantially no adhesive properties are used in the sealing material, sufficient protection against urinary leakage is provided by the incontinence device 10 of this invention.

[0028] The cap preferably is symmetrical about a central axis 40 shown in FIGS. 2 and 3 although it need not be symmetrical in all embodiments.

[0029] The sealing material 30 can be known adhesives which are nonirritating to the body and can be used in contact with the body over a period of time. Such adhesives include the water soluble paste FIXADENT® or CONFIDENT an adhesive produced by Block Drug of Jersey City, New Jersey. However, sealing materials such as conventional lubricants including petrolatum or petroleum jelly such as Vaseline® can be used without adhesive properties. The sealing material such as petroleum jelly compensates for irregularities in the skin or cap sealing surface flange and thus provides for protection against air and urine leakage in use of the device when the device is applied to the body.

[0030] The sealing material 30 can be applied by the user using a Q-tip applicator or the fingertip to rub the vaseline or adhesive over the body sealing surface just prior to use. In some cases, the lubricant or adhesive can be prepositioned on the device with a cover or release strip 31 applied thereover to prevent sticking or removal of the sealant or adhesive prior to application. In some cases, a plurality of sealant and cover strips can be used as suggested in FIG. 4 at 32 and 33. Thus, in the first application, the lower strip 33 is removed exposing an underlying surface 32 of adhesive or lubricant sealing material for a first application to the body. This can be done where the sealant directly contacting the flange directly is an adhesive and, thus, the product is maintained on the body. After first removal, the second cover strip 31 can be removed to expose the underlying adhesive 30 for a second application. Any number of protective strips and sealant layers can be used as desired. In the preferred embodiment, the sealant material is applied just prior to use by the user as when vaseline petroleum jelly is used.

[0031] FIGS. 5 and 6 diagrammatically show placement on the body. In FIG. 5, the labia 41 are diagrammatically illustrated with the urethral opening or meatus 42 being shown with the flange 13 positioned thereover. In FIG. 6, the cap 10 is shown in position with the skin of the body about the meatus pulled into direct contact with the body contacting surface 18 of the flange and the underside of the frustoconical portion 14. This closes the urethral orifice and the positioning of the skin below the flange acts to aid in centering and maintaining the cap in position on the body as well as to prevent urine outflow. Similarly, because the flange 13 is positioned to lie substantially just within the labia 41 at a planar area around the meatus, positioning is maintained and this spacing aids in locating and placing the urethral cap in position.

[0032] In the method of applying the urethral cap of this invention, the cap is deformed inwardly by the fingers of the user and then applied to the orifice of the urethra and allowed to expand to its original shape as shown in FIG. 2. This creates a vacuum within the inner chamber 12 causing outside atmospheric pressure to push against the flange 13 and frustoconical portion 14 and maintain the urethral cap in good sealing engagement with the body. The skin or tissue immediately surrounding the meatus is compressed by the air pressure difference and a seal is formed with the cap 10 at the surface 141. The sealing material pre-applied to the

body-contacting surface aids in maintaining the seal. The pressure differential between the inside of the cap and the atmosphere can vary greatly. This depends in part on atmospheric conditions, as well as how much depression is applied to the chamber before it resiliently returns to its normal position shown in Figure 2. In some cases, the full repositioning of Figure 2 is not achieved after compression of the side wall in application, but in all cases, some chamber vacuum or partial vacuum remains inside the cap. The interior chamber 12 can act as a reservoir if there is some leakage while the cap is in place, although this does not normally occur.

[0033] As previously noted, the skirt size is such that it aids in positioning the skirt in proper position over the urethral orifice, and also maintaining the cap in place. The finger grip is important for placement particularly in older patients. The finger grip can be simply the cylindrical outer surface of chamber 12.

[0034] The differential in air pressure between the inside of the cap and the atmosphere is difficult to determine. In many cases, the air pressure differential may be as little as 6900 Pa (1 psi), or can be 13800-34500 Pa (2-5 psi) or 41400-690000 Pa (6-10 psi) or more. Preferably, the pressure is applied by the depression of the cap and the expansion thereof towards its original shape since the walls are resiliently deformable. This can result in different amounts of pressure when even the same cap is used depending on how it is applied and how much depression occurs. Surprisingly, it has been found that, even with small caps, following the method of this invention, sufficient air pressure difference is obtained to maintain the cap in position and avoid urine flow.

[0035] Thus, a user can alleviate urinary incontinence such as stress incontinence by applying the cap over the urethral orifice using the labia spacing to help position the cap. Prior to contact with the body, the cap is resiliently depressed at the hand gripping portion and the encircling flange is brought into contact with the skin surrounding the orifice opening. The body contacting portion of the flange has been previously treated with petroleum jelly or an adhesive as previously described. Slight pressure on the skin and release of the pressure deforming the cap causes a suction within the cap and provides the air pressure difference on the outside of the flange and frustoconical portion 14 that maintains the cap in place on the body and closes the meatus as shown in Fig. 6. The cap can be easily removed to allow voiding when desired. In some cases, the cap can merely be pulled off the skin although a slight depression of the finger gripping portion is desired to alleviate the pressure difference first. The device is comfortable in use, can be easily applied by a majority of patients and has been found to prevent urinary leakage and thus alleviate urinary incontinence in women, including stress urinary incontinence.

[0036] In the preferred embodiment, the cap is packaged in a surrounding clear plastic container or envelope diagrammatically illustrated at 50. This maintains the cleanliness of the cap prior to usage. Such envelopes are known in the art and can comprise thin plastic films which can be see through or opaque. Other conventional packages can be used to store and transport the urethral cap to maintain cleanliness. In some cases, a plurality of caps can be packaged in a single package or no package need be used. In some cases, the caps of this invention can be sterilized. Preferably, the caps 10 of this invention are manufactured and packaged under and meeting ISO 9000 standards to provide cleanliness, manufacturing quality and lot control. Thus, contamination, including bacterial contamination, is minimized.

[0037] The urinary caps of this invention can be sterilized to reduce the risk of infection or irritation to the skin. Sterilization is not required since the device is external to the body and does not have any component passing within the urethra.

[0038] It has been found that caps of this type are useful for long periods of time and maintain the contact with the skin in sealing arrangement for periods of 2 to 6 hours or more in some cases.

[0039] While specific embodiments of this invention have been shown and described, it will be obvious to those skilled in the art that many variations are possible. The particular materials, integral nature, geometric configuration of the devices of this invention can vary greatly. In all cases, a pressure differential is instrumental in providing a body contacting seal to alleviate conditions of incontinency which seal acts along with a mechanical closure of the meatus. The seal formed by the flange 13, portion 14 and the body by the air pressure difference between the chamber and atmosphere and the adhesive contact if used, is sufficiently strong to withstand and to prevent urinary flow out of the cap over long periods of time at urinary pressures normally encountered at the urethral orifice.

Claims

1. A urethral cap (10) for alleviating urinary incontinence when applied over the meatus of the body of a user, the cap comprising a resilient, at least partially-deformable cap body (11) having a hand gripping portion (17), the cap body defining a chamber (12) therewithin sized to allow for reciprocal resilient deformation of the cap body to provide a vacuum therein to hold the urethral cap on the body of the user, and to close the meatus of the body of the user, the chamber defining a central axis (40) passing from the top of the cap to the bottom of the cap, the cap body defining, at its bottom, an encircling flange (13) having a body-contacting surface (18) to act as a sealing surface with the body of the user, thereby closing the meatus of the user by compression, wherein the cap carries a sealing material (30) over

the body-contacting surface for aiding in preventing liquid flow between the body-contacting surface and the body of the user when the cap is in use, **characterised in that** the cap provides a generally frustoconical inner surface adjacent to the body-contacting surface to aid in closing the meatus by compression.

2. A urethral cap as claimed in claim 1, wherein the encircling flange (13) has an outer diameter of from substantially 2.3 to substantially 3.4 centimetres.

3. A urethral cap as claimed in claim 2, wherein the encircling flange (13) has an outer diameter of substantially 3 centimetres.

4. A urethral cap as claimed in any one of claims 1 to 3, wherein the bottom of the cap (10) is defined by the encircling flange (13), and the height of the cap from its top to its bottom is substantially 2 centimetres.

5. A urethral cap as claimed in any one of claims 1 to 4, wherein the cap (10) is integrally formed of a resilient material which allows ease of application to the body of the user by deforming the cap chamber (12), applying the cap to the body of the user about the orifice of a urethra, and releasing said deforming pressure to define an air pressure difference between the chamber (12) and the atmosphere sufficient to seal the flange (13) to the user, and to prevent liquid flow therethrough at normal pressures encountered in urinary fluids expressed by the body, the cap further defining a meatus-constricting surface to close the meatus when the cap is applied with said pressure difference acting to position the cap.

6. A urinary cap as claimed in any one of claims 1 to 5, wherein the cap (10) is formed of an FDA-approved silicone rubber.

7. A urinary cap as claimed in any one of claims 1 to 6, wherein the cap (10) carries a layer of the sealing material (30) over the body-contacting surface (18), and wherein a release strip (31) covers the sealing material.

8. A urethral cap as claimed in claim 7, further comprising a second layer of sealing material (32) over the release strip (31), and a second release strip (33) overlying the second layer of sealing material.

9. A urethral cap as claimed in any one of claims 1 to 8, wherein the sealing material (30) is a lubricant with no adhesive properties.

10. A urethral cap as claimed in any one claims 1 to 8, wherein the sealing material (30) is an adhesive.

11. A urethral cap as claimed in any one of clams 1 to 10, wherein the cap (10) conforms to ISO 9000 manufacturing standards.

12. A urethral cap as claimed in claim 11, wherein the cap (10) is packaged in accordance with ISO 9000 manufacturing standards.

13. A urethral cap as claimed in any one of claims 1 to 12, wherein the cap (10) is integrally formed of a silicone rubber material compatible with, and non-irritating to, the skin of the body of the user.

Patentansprüche

1. Harnröhrenkappe (10) zur Linderung von Harninkontinenz bei Anwendung über der Meatus des Körpers einer Benutzerin, umfassend einen elastischen, mindestens teilweise verformbaren Kappenkörper (11) mit einem Handgriffabschnitt (17), wobei der Kappenkörper eine Kammer (12) darin definiert, welche derart bemessen ist, dass sie eine elastische Hin- und Herverformung des Kappenkörpers ermöglicht, um ein Vakuum darin zum Halten der Harnröhrenkappe auf dem Körper der Benutzerin zu liefern, und zum Schließen der Meatus des Körpers der Benutzerin, wobei die Kammer eine Mittelachse (40) definiert, welche von der Oberseite der Kappe zur Unterseite der Kappe verläuft, wobei der Kappenkörper an der Unterseite davon einen umgebenden Flansch (13) mit einer Körperkontaktfläche (18) definiert, welche als Dichtungsfläche mit dem Körper der Benutzerin dient, wodurch der Meatus der Benutzerin geschlossen wird durch Kompression, wobei die Kappe ein Dichtungsmaterial (30) über der Körperkontaktfläche trägt, um ein Verhindern eines Flüssigkeitsflusses zwischen der Körperkontaktfläche und dem Körper der Benutzerin zu unterstützen, wenn die Kappe im Einsatz ist, **dadurch gekennzeichnet, dass** die Kappe eine generell kegelstumpfartige Innenfläche neben der Körperkontaktfläche aufweist, um ein Schließen der Meatus durch Kompression zu unterstützen.

2. Harnröhrenkappe nach Anspruch 1, wobei der umgebende Flansch (13) einen Außendurchmesser von im Wesentlichen 2,3 bis im Wesentlichen 3,4 cm aufweist.

3. Harnröhrenkappe nach Anspruch 2, wobei der umgebende Flansch (13) einen Außendurchmesser von im Wesentlichen 3 cm aufweist.

4. Harnröhrenkappe nach einem der Ansprüche 1 bis 3, wobei die Unterseite der Kappe (10) definiert ist

durch den umgebenden Flansch (13) und die Höhe der Kappe von deren Oberseite zu deren Unterseite im Wesentlichen 2 cm beträgt.

5. Harnröhrenkappe nach einem der Ansprüche 1 bis 4, wobei die Kappe (10) einstückig gebildet ist aus einem elastischen Material, welches eine einfache Anwendung auf den Körper der Benutzerin ermöglicht durch Verformen der Kappenkammer (12), Anwenden der Kappe auf den Körper der Benutzerin um die Öffnung einer Harnröhre und Lösen des Verformungsdrucks zum Definieren eines Luftdruckunterschieds zwischen der Kammer (12) und der Atmosphäre, welcher ausreicht, den Flansch (13) gegen die Benutzerin zu dichten und ein Durchfließen der Flüssigkeit bei Normaldrücken, welche in vom Körper abgegebenen Harnflüssigkeiten auftreten, zu verhindern, wobei die Kappe ferner eine den Meatus einengende Fläche zum Schließen des Meatus bei Anwendung der Kappe mit einem Druckunterschied, welcher zur Positionierung der Kappe dient, definiert.

6. Harnröhrenkappe nach einem der Ansprüche 1 bis 5, wobei die Kappe (10) aus einem FDA-zugelassenen Silikongummi besteht.

7. Harnröhrenkappe nach einem der Ansprüche 1 bis 6, wobei die Kappe (10) eine Schicht des Dichtungsmaterials (30) über der Körperkontaktfläche (18) trägt, und wobei der Lösestreifen (31) das Dichtungsmaterial bedeckt.

8. Harnröhrenkappe nach Anspruch 7, ferner umfassend eine zweite Schicht eines Dichtungsmaterials (32) über dem Lösestreifen (31) und einen zweiten Lösestreifen (33) über der zweiten Schicht des Dichtungsmaterials.

9. Harnröhrenkappe nach einem der Ansprüche 1 bis 8, wobei das Dichtungsmaterial (30) ein Schmiermittel ohne Hafteigenschaften ist.

10. Harnröhrenkappe nach einem der Anspräche 1 bis 8, wobei das Dichtungsmaterial (30) ein Haftmittel ist.

11. Harnröhrenkappe nach einem der Ansprüche 1 bis 10, wobei die Kappe (10) den ISO 9000 Herstellstandards entspricht.

12. Harnröhrenkappe nach Anspruch 11, wobei die Kappe (10) gemäß den ISO 9000 Herstellstandards verpackt ist.

13. Harnröhrenkappe nach einem der Ansprüche 1 bis 12, wobei die Kappe (10) einstückig gebildet ist aus einem Silikongummimaterial, welches für die Haut des Körpers der Benutzerin verträglich ist und diese nicht reizt.

Revendications

1. Capuchon urétral (10) pour soulager l'incontinence urinaire lorsqu'il est appliqué sur le méat du corps d'un utilisateur, le capuchon comprenant un corps de capuchon (11) élastique et au moins partiellement déformable présentant une partie de préhension manuelle (17), le corps de capuchon définissant une chambre (12) à l'intérieur de celui-ci dimensionnée pour permettre la déformation élastique réciproque du corps de capuchon afin d'établir un vide intérieur destiné à maintenir le capuchon urétral sur le corps de l'utilisateur et fermer le méat du corps de l'utilisateur, la chambre définissant un axe central (40) s'étendant du sommet du capuchon vers la partie inférieure du capuchon, le corps de capuchon définissant, au niveau de sa partie inférieure, un anneau de ceinturage (13) présentant une surface de contact corporel (18) destinée à agir en tant que surface d'étanchéité avec le corps de l'utilisateur, fermant ainsi le méat de l'utilisateur par compression, la surface du capuchon en contact avec le corps étant garnie d'une matière d'étanchéité (30) pour éviter encore plus l'écoulement de liquide entre la surface en contact avec le corps et le corps de l'utilisateur lorsque le capuchon est utilisé, **caractérisé en ce que** le capuchon forme une surface interne généralement tronconique adjacente à la surface en contact avec le corps pour assister la fermeture du méat par compression.

2. Capuchon urétral selon la revendication 1, **caractérisé en ce que** l'anneau de ceinturage (13) présente un diamètre externe compris sensiblement entre 2,3 et 3,4 centimètres.

3. Capuchon urétral selon la revendication 2, **caractérisé en ce que** l'anneau de ceinturage (13) présente un diamètre sensiblement égal à 3 centimètres.

4. Capuchon urétral selon l'une quelconque des revendications 1 à 3, **caractérisé en ce que** la partie inférieure du capuchon (10) est délimitée par l'anneau de ceinturage (13), et **en ce que** la hauteur du capuchon depuis son sommet jusqu'à sa partie inférieure est sensiblement égale à 2 centimètres.

5. Capuchon urétral selon l'une quelconque des revendications 1 à 4, **caractérisé en ce que** le capuchon (10) est formé d'une seule pièce en une matière élastique qui permet une application aisée sur le corps de l'utilisateur par déformation de la chambre (12) du capuchon, application du capuchon sur

le corps de l'utilisateur au niveau de l'orifice de l'urètre, et relâchement de la pression de déformation pour définir une différence de pression d'air entre la chambre (12) et l'atmosphère suffisante pour ajuster l'anneau de ceinturage (13) de manière étanche au corps de l'utilisateur, et pour empêcher l'écoulement de liquide à travers celui-ci à des pressions normales rencontrées pour des fluides urinaires évacués par le corps, le capuchon définissant en outre une surface de constriction du méat pour fermer le méat lorsque le capuchon est appliqué, la différence de pression agissant pour positionner le capuchon.

6. Capuchon urétral selon l'une quelconque des revendications 1 à 5, **caractérisé en ce que** le capuchon (10) est réalisé en un caoutchouc de silicone approuvé par la Food and Drug Administration (FDA).

7. Capuchon urétral selon l'une quelconque des revendications 1 à 6, **caractérisé en ce que** le capuchon (10) comporte une couche de matière d'étanchéité (30) sur la surface en contact avec le corps (18) et **en ce qu'**une pellicule détachable (31) recouvre la matière d'étanchéité.

8. Capuchon urétral selon la revendication 7, **caractérisé en ce qu'**il comporte en outre une seconde couche de matière d'étanchéité (32) sur la pellicule détachable (31), et une seconde pellicule détachable (33) recouvrant la seconde couche de matière d'étanchéité.

9. Capuchon urétral selon l'une quelconque des revendications 1 à 8, **caractérisé en ce que** la matière d'étanchéité (30) est un lubrifiant sans propriétés adhésives.

10. Capuchon urétral selon l'une quelconque des revendications 1 à 8, **caractérisé en ce que** la matière d'étanchéité (30) est un adhésif.

11. Capuchon urétral selon l'une quelconque des revendications 1 à 10, **caractérisé en ce que** le capuchon (10) est conforme à la norme de fabrication ISO 9000.

12. Capuchon urétral selon l'une quelconque des revendications 1 à 11, **caractérisé en ce que** le capuchon (10) est conditionné selon la norme de fabrication ISO 9000.

13. Capuchon urétral selon l'une quelconque des revendications 1 à 12, **caractérisé en ce que** le capuchon (10) est formé d'une seule pièce dans une matière en caoutchouc de silicone compatible avec, et non irritative pour, la peau du corps de l'utilisateur.

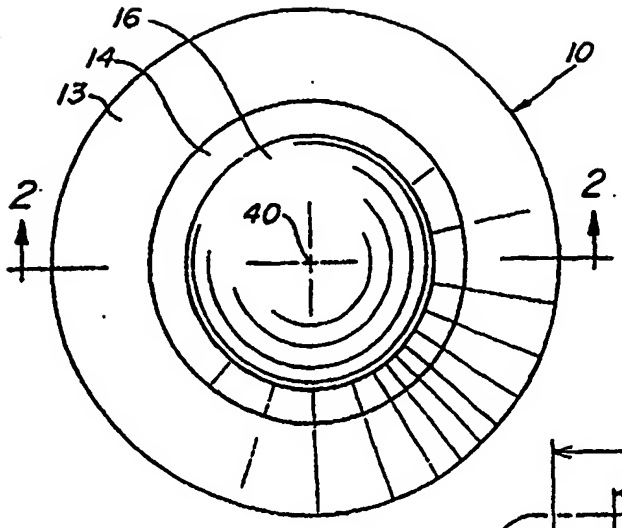


Fig. 1

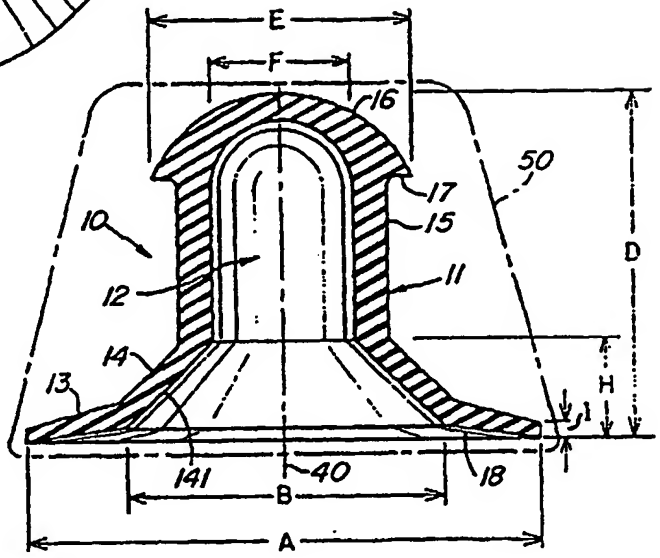


Fig. 2

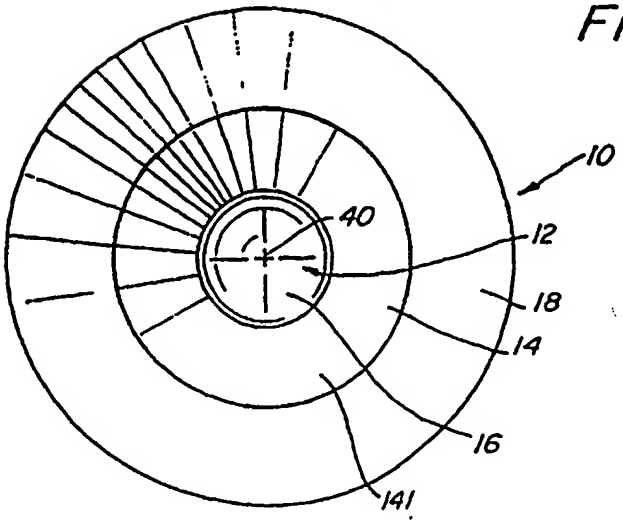


Fig. 3

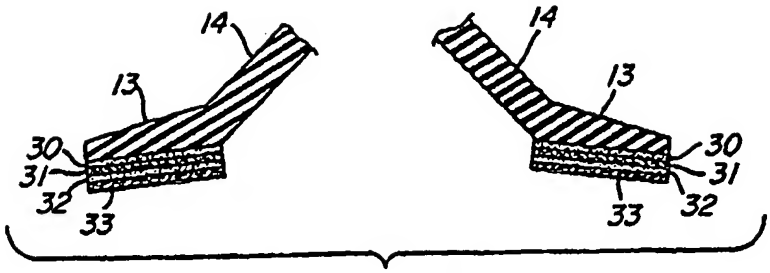


Fig. 4

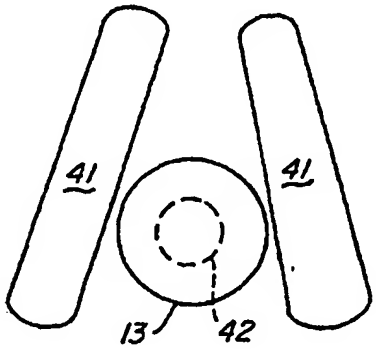


Fig. 5

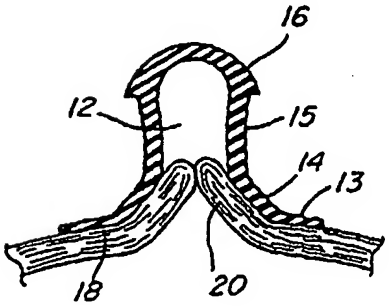


FIG. 6

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 321 111 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
25.06.2003 Bulletin 2003/26

(51) Int Cl.[7]: **A61F 2/06**, A61M 25/00

(21) Application number: **03075155.6**

(22) Date of filing: **20.03.1996**

(84) Designated Contracting States:
DE FR GB IT NL

(30) Priority: **20.03.1995 US 407297**
26.12.1995 US 579592

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
96301891.6 / 0 733 379

(71) Applicant: **ContiCare Medical, Inc.**
Eden Prairie, MN 55347 (US)

(72) Inventor: **Tihon, Claude**
Eden Prairie, Minnesota 55437 (US)

(74) Representative: **Charig, Raymond Julian et al**
Eric Potter Clarkson,
Park View House,
58 The Ropewalk
Nottingham NG1 5DD (GB)

Remarks:
This application was filed on 16 - 01 - 2003 as a divisional application to the application mentioned under INID code 62.

(54) Self-cleansing bladder drainage device

(57) An urethral drain having deep external drainage channels, a low-profiled bladder retention segment, and a reversibly detachable collection segment, facilitates the draining of urine and fluids from the bladder. The low-profiled retention means minimizes bladder irritations and the deep external channels reduce the occurrence of infections. Incorporation of a reduced diameter smooth segment on the catheter, proximate the location of the external urethral sphincter allows the patient to void normally and at will. Modifying the size of this smooth segment aids the function of a defective sphincter in controlling urine leakage. The drain can be worn concealed within the urethra. Flushing action from normal voiding washes out particulate matters in the urethra and the concealed drain further minimizes contamination. Together, these features improve quality of life for patients needing catheterization.

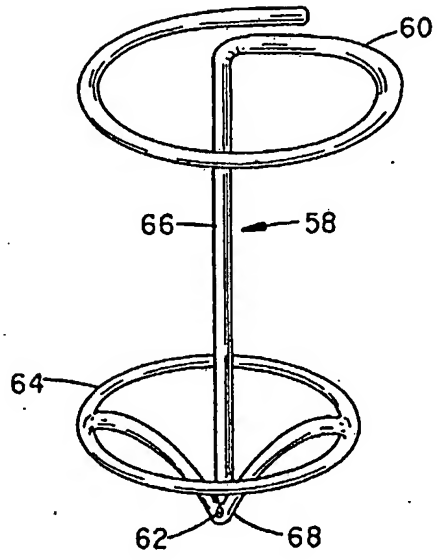


FIG. 12

EP 1 321 111 A2

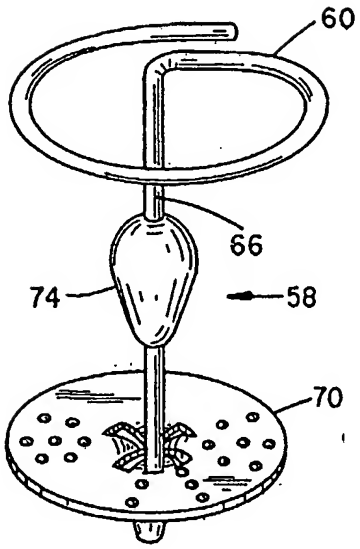


FIG. 14

Description

BACKGROUND OF THE INVENTION

I. Cross Reference to Related Application:

[0001] This application is a continuation-in-part of application serial no. 08/407,297, filed March 20, 1995, and entitled "SELF-CLEANSING BLADDER DRAINAGE DEVICE".

II. Field of the Invention:

[0002] This invention relates generally to body fluid drainage devices, and more particularly to a urinary drain having improved performance characteristics.

III. Discussion of the Prior Art:

[0003] Urethral catheters, such as the Foley catheter, now used for bladder drainage are essentially elongated tubular structures placed in the urethra for draining urine through the central lumen thereof. Near the distal end of the tube is an inflatable balloon which, when inflated while in the bladder, allows the catheter to be held in place. Its proximal end has a drainage port as well as a balloon inflation port. The proximal end of the catheter protrudes beyond the urethral orifice and can be attached to a bag receptacle for the collection of the near constantly dripping urine from the bladder. The collection bag is either attached to the patient's leg when the patient is ambulatory, or to the side of the bed during bed rest. At times, a plug is used in place of the bag to stop the leakage of urine from the catheter tip.

[0004] When Foley catheters or the like are used, patients are not able to void when they want to. Rather, urine is continuously drained from the bladder through the central lumen of the elongated tube and into the collection bag. Ambulatory patients are therefore obligated to have the leg bag attached to their leg, and this poses a source of great inconvenience, unsightliness and problems affecting their quality of life. Due to the fact that urine is continuously being drained from the bladder, the bladder is continuously near empty. The dome of the bladder, therefore, rests continuously on the water-filled bulging balloon retention part of the Foley catheter, causing tissue compression, irritation and erosion related adverse side effect problems. Furthermore, increased urinary tract infection is common with patients using such catheters, especially when used on a chronic basis. Though the causal factors have not been precisely identified, length of time of catheterization has been associated with an increased frequency and severity of urinary tract infection, presumably due to the migration of bacteria up the urethral tract. Frequently, yellow encrusted and mucoid proteinaceous depositions containing bacteria are found on the surfaces of the catheter with much higher concentration on the inner lumen surfaces. The mandated usage of urine receptacles causes additional associated stigma of soiled clothing, furniture and odor.

[0005] The Spinosa et al. Patent 3,815,608 discloses in Figure 9 thereof a typical Foley urinary catheter having an inflatable balloon 64 for retaining the distal end portion of the catheter with its drainage hole 56 within the urinary bladder. An alternative embodiment disclosed in Figures 6 and 7 of the Spinosa et al. patent depicts a urinary catheter that uses a helically threaded region thereof as the retention means in place of an inflatable balloon. This device still relies upon the central lumen 46 as the urine path while the channels 48 define between the helical threads 44 allow for "drainage of exudate discharged from the prostate gland".

SUMMARY OF THE INVENTION

[0006] The present invention provides a solution to increase the quality of life for patients who require drainage catheters by solving compression and irritation related problems, giving patients an option to carry on their daily lives more normally
and reduce incidence of the common urinary tract infections. One embodiment of the invention comprises a bladder drainage device having at least one deep, open fluid-drainage channels and a low profile bladder retention means at its distal end. In addition, it can contain an essentially smooth segment, preferably narrowed, in the area of the external urethral sphincter. Urine drains from the bladder, via the open surface channels. The narrowed smooth segment permits the external urethral sphincter to function normally to shut off the leakage of urine from the bladder to the lower portion of the urethra. The drainage channels reappear below the external sphincter. When the sphincter opens, urine and fluid will flow past the relaxed sphincter area at the smooth, narrowed drain region, and down to the deep surface drainage channels below. Unlike the situation with the Foley type catheter and the catheter of Figures 6 and 7 of the Spinosa et al. '608 patent, where urine is continuously drained in a leaking fashion from the bladder through an internal lumen of the drainage catheter, the present configuration of the invention allows urine to be stored in the bladder until voided in mass, much as in a normal manner, when the patient is ready to do so. Due to this natural and daily multiple automatic flushing action in the urethra and channel walls by a rushing of the bolus of urine, the bladder drain of the present invention is self-cleansing without any added external pressurized flushing equipment means, such as that described in U. S. Patent No. 4,723,946, or any added steps for the patient.

[0007] The device of the present invention, without the smooth segment, can be worn by patients in cases where constant urine drainage is required or unavoidable. Thus, the drain will have the benefits of the lower profile retention means for reduced bladder irritability,

and the deep external drainage channel(s) causing urine flow to be in contact with the urethral wall to minimize colonization of bacteria and other contaminants within a lumen, thus lower possibility of infections.

[0008] The presence of the narrow, smooth segment at the site of the external urethral sphincter region allows the natural constriction of the external urethral sphincter to terminate the flow of fluid to the distal bulbous and penile urethra as the sphincter normally functions. The patient is, therefore, able to control his own voiding frequency. This permits the drain device to be worn by ambulatory patients without the necessity of an external urine drainage collection leg bag.

[0009] Patients suffering from urinary incontinence have differing degrees of contractibility of the external urinary sphincter, depending upon age and other factors. By providing a smooth surface section that can be repositioned along the length of the externally grooved drain member and which can be selected for its outer diameter, a variety of patients can be accommodated.

[0010] The distal end of the drain device located within the bladder contains a retention means for retaining it at the bladder neck. This preferably a coiled section of the flexible, deep open channeled drainage device, which is initially straightened for insertion in the urethra by a straightening stylet placed in a central lumen of the drain device. Removing the wire after drain placement restores the curl. Due to the fact that the low profile retention means is an extension of the drainage segment, no balloon is needed, nor is there a necessity for a perpendicular, upward-protruding tubing with lateral openings for the passage of urine. The retention means is spaced apart from the smooth narrowed section a distance to assure drainage within the prostatic urethra. Before exiting the urethra, the deep channels are replaced by a traditional tubular structure, the collection segment, which proceeds to exit the urethra. This collection segment collects fluid from the deep external channel(s) above, transports it beyond the meatus of the penis, and permits the attachment of a urine drainage collection bag or a plug at the proximal end. The tubular collection segment can be detached from the channeled main drain body, thus leaving the entire drain device concealed inside the urethra. This further insures minimal infection from outside contamination, and avoids the aesthetically displeasing and uncomfortable presence of an external device.

[0011] Given the anatomical differences between the urinary systems in males and females, and in particular the short length and shape configuration of the female urethra, the drainage device for a female patient preferably comprises a soft, flexible, plastic body member having a flat coil bladder retention means at its distal end and a corresponding retention means at its proximal end to prevent the device from migrating upward into the bladder. The proximal retention device is configured to conform to the vestibule proximate the urethral opening. It is preferably an open structure or perforated to permit exposure of the underlying tissue to air.

[0012] In addressing female stress incontinence, a cuff member of a chosen size appropriate for the patient may be placed about the drain member to cooperate with the urinary sphincter, allowing the sphincter to create an improved seal against the cuff to block urine flow.

[0013] Thus, the object of this invention is to greatly increase the quality of life for patients who require bladder drainage catheters.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The foregoing features and advantages of the invention will become apparent to those skilled in the art from the following detailed description of the present invention, in which numerals in the several view refer to corresponding parts.

Figure 1 is an elevational view of a bladder drain in accordance with a first embodiment of the invention;

Figure 1(a) is a partial view of the bladder drain of Figure 1, but with an alternative anchoring structure;

Figure 2 is an elevational view of an alternative embodiment of the bladder drain in accordance with the invention;

Figure 3 is a view illustrating the embodiment of Figure 2 inserted in the male urethra;

Figure 4 is a fragmentary, enlarged perspective view of the portion of a bladder drain, illustrating two straight surface grooves;

Figure 5 is a fragmentary, enlarged perspective view of a portion of a bladder drain illustrating spiral surface grooves;

Figure 6 is an enlarged cross-sectional view of a portion of the body of a bladder drain having four surface grooves extending the length thereof;

Figure 7 is an enlarged cross-sectional view through a portion of the body of a bladder drain having three surface grooves extending along the length dimension thereof;

Figure 8 is an enlarged cross-sectional view through a portion of the body of a bladder drain having a positionable smooth sleeve segment affixed thereto;

Figure 9 is a partially sectional, fragmentary view of the embodiment of Figures 1 or 2 proximate the junction between the grooved bladder drain element and its associated collection segment;

Figure 9(a) is an exploded, partial, sectional view of a drain member having straight (non-spiral) surface grooves and a collection tube used therewith;

Figure 10 is an enlarged, partial, perspective view of a segment of the drain of Figure 7 and incorporating retention rings thereon;

Figure 11 is a partial side elevation of a drain device having the configuration of Figure 7 and illustrating

an alternative drain retention feature.

Figure 12 illustrates an alternative embodiment of the invention for placement in the female urethra;

Figure 13 illustrates the device of Figure 12 but with an alternatively configured proximal retention means;

Figure 14 illustrates the device of Figures 12 or 13 with a cuff member placed thereon when treating female stress incontinence; and

Figures 15a, b and c illustrate alternative shapes for the cuff member illustrated in Figure 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0015] Referring first to Figure 1, there is shown a perspective view of a bladder drainage device in accordance with a first embodiment of the invention. It is indicated generally by numeral 10 and is seen to comprise an elongated, flexible tubular member 12 having a proximal end 14 and a distal end 16 and with a stylet receiving lumen 18 extending longitudinally toward but just short of the distal end 16. Thus, the distal end 16 covers the stylet lumen precluding the flow of body fluids therethrough when the drainage device 10 of the present invention is in place within the urethra of a patient.

[0016] With continued reference to Figure 1, the body member 12 of the drainage device 10 is shown as including at least one channel 20 formed in the surface thereof and it extends substantially the entire distance from the proximal end 14 to the distal end 16. In Figure 1, the channel 20 is shown as spirally traversing the drain body 12, but it is to be understood that the channel or channels may be straight, as well. With no limitation intended, for a drain device having an outside dimension of 0.21 inches, the helical channel 20 may have a depth of approximately 0.06 inches. The body member is preferably fabricated from a flexible polymer material, such as silicone, silastic, polyurethane or another thermoplastic elastomer having a durometer shore hardness between about 30 and 95 shore A.

[0017] Disposed proximate the distal end of the bladder drain device is a bladder retention segment 22 which comprises a curled end portion which can be straightened by the full insertion of a wire stylet (not shown) through the lumen 18. However, when the stylet is fully withdrawn following insertion of the drain assembly as shown in Figure 1 into the urethra with the distal portion within the bladder, the memory property of the plastic comprising the distal end portion of the drainage device 10 allows the preformed distal end, bladder-retaining portion 22, to form a loop or curl as illustrated. Those skilled in the art can appreciate that means other than a controlled memory property are available for creating the curl on the distal end of the drainage device. For example, a short wire segment having a preformed shaped can be embedded into the body of the drain to enhance the formation of the curl upon extraction of the stylet.

[0018] Attached to the proximal end of the bladder drain 10 is a fluid collection segment, indicated generally by numeral 24. The fluid collection segment 24 may be attached and detached from the drainage segment 12 in a manner that will be described later herein. In its simplest form, the collection segment 24 comprises an elongated plastic tube having an internal lumen extending from the proximal end 14 of the drain segment 10 to an open distal end 28 which forms the drain outlet. The collection segment 24 can accept a drainage bag or a plug not shown.

[0019] To facilitate removal of the drain, a strand such as a monofilament nylon line 25, is fixedly secured to the proximal end 14 of the drain 12 and extends beyond the proximal end 28 of the collection segment 24 and out the urethral opening in the penis. By grasping the monofilament line 25 by the loop 27 and pulling on the line, the memory property of the fixation member 22 is overcome and the drain can be readily pulled through the urethra and out the end of the penis. If desired, the line 25 may terminate short of the proximal end 28 of the collection segment 24 and in that event, an instrument having a hook on it may be passed up the lumen of the collection segment 24 to grasp a loop 29 tied in the line. By now pulling on the instrument, the drain member 12 can again be removed.

[0020] An alternative embodiment of the invention is depicted in Figure 2. The assembly of Figure 2 is similar in most respects to the embodiment of Figure 1 except that in the drain device 30 of Figure 2, the tubular member 12 includes a narrowed and smooth (non-channeled) segment 32 for cooperating with the external sphincter of the urethra. At the distal end of the segment 32 is a tapered shoulder 35 and at the proximal end is a more squared shoulder 36. The length of segment 32 is preferably in the range of from 0.5 cm to 5.0 cm and its outer diameter may be from 0.1 to 2.0 cm.

[0021] Referring next to Figure 3, it shows the bladder drain device 30 of the embodiment of Figure 2 disposed in the male urethra. The bladder retention portion 22 is located proximate the neck of the bladder 34 and with the installation stylet (not shown) fully removed, the bladder retention portion assumes its flat spiral configuration, thereby holding the drainage device in place. The portion of the drainage device 30 located above the tapered shoulder 34 is dimensioned to traverse the prostate 36 and with the zone 32 of reduced diameter extending through the external urethral sphincter 38. If desired, a string or monofilament 25 can be co-extruded with the drain device of Figure 2 to inhibit stretching of the device in zone 32 when tensile forces are applied during removal of the drain.

[0022] The spiral curl 22 comprising the retention element is essentially perpendicular to the axial length of the drain and does not protrude appreciably above the base of the bladder. This low, flat profile distinguishes the present invention from the common Foley catheter,

which is retained by means of a liquid filled balloon, as well as from the device shown in U.S. Patent No. 4,738,667 to Galloway. The removal of a straightening stylet, as compared to the removal of an outer shield in the Galloway device, serves to minimize any irritation to the urethral wall of the patient. The use an internal straightening wire, as contrasted to a design utilizing an external straightening sleeve, also allows the existence of deeper drainage channels for a given outer diameter of the drain itself. While the bladder retention segment is depicted as a spiral or curl at the distal end of the body member 12 comprising the drain, it can be appreciated that an inflatable balloon adhered to the exterior of the tubular body 12 and communicating through a port bridged by the balloon leading to an inflation lumen may be employed to anchor the drain in a fashion similar to what is conventionally used with a Foley catheter. Such an arrangement is shown in Figure 1a, with the silastic balloon identified by numeral 39.

[0023] With the embodiment of Figure 2 in place, as illustrated in Figure 3, there will be a continuous flow of urine from the bladder 34 through the channel 20 formed in the exterior wall of the drain segment 30 with the channel emptying into the lumen of the urine collection tube 24. For patients having a functioning external urethral sphincter 38, the compressional force on the urethra in the zone 32 of the drain will close the urethra against that segment thereby blocking urine flow. When the patient desires to drain his or her bladder, he or she voluntarily relaxes the external urethral sphincter 38, allowing the contents of the bladder 34 to flow through the channel(s) formed in the wall surface of the drainage device 30 to again empty into the urine collection tube 24 leading to a collection bag (not shown).

[0024] Figures 4 through 7 are included to show alternative ways of configuring the drainage segments 10 and 30 illustrated in Figures 1 and 2, respectively. In Figure 4, the drainage segment 12 includes two straight longitudinal channels 40 and 42, diametrically opposed from one another, that extend substantially the entire length of the drainage segment. Also visible in Figures 4 through 7 is the stylet lumen 18. In the embodiment of Figure 5, the surface grooves, as at 20, form a spiral, as in the embodiments of Figures 1 and 2. This spiral pattern may conveniently be formed during the fabrication process by twisting the segment 12 during the extrusion process prior to cooling. By controlling the amount of twisting, the pitch of the channels can be controlled.

[0025] While linear channels of the type shown in Figure 4 may be provided in the drainage segment, a spiral channel configuration is preferred in that the lateral projections on the outer surface of the drain will interact with the urethral wall in such a fashion as to retard movement of the drain along the axial length of the urethra, thus minimizing undesired migration thereof. The side walls of the channels are preferably undercut or dished, as at 44 (Figure 6), to thereby prevent irritation of the urethra, and to inhibit invagination of the urethral wall tissue into the channels.

[0026] Figures 6 and 7, respectively, show cross-sectional views of the drain in which four and three channels, respectively, extend the length thereof.

[0027] Referring to the cross-sectional view of Figure 8, another way of forming a smooth segment along the length of the drainage member 12 for cooperating with the external urinary sphincter of a given patient is to provide a short length of tubing, as at 45, having an internal lumen whose side walls are complimentary in shape to the exterior surface of the grooved drainage member 12. Thus, the smooth portion of the tube 45 can be longitudinally adjusted to a location along the drain body where the urinary sphincter is located for that patient. Also, the outside diameter of the removable and replaceable smooth tubular segment 45 can be selected to accommodate the particular contractibility of the urinary sphincter of the patient to provide increased continence and will usually be in the range of from 0.3 cm to 1.0 cm.

[0028] It is further contemplated that the smooth tubular member 45 on the female urethral drain can comprise an inflatable sleeve surrounding the drain member 12 (Fig. 1). This is deemed to be beneficial in cases of female stress incontinence in that the sleeve can be inflated after placement to a degree effective to preclude leakage between the expandable sleeve and the neck of the bladder and to compensate for sphincter deficiency.

[0029] Referring now to Figure 9, there is shown an enlarged fragmentary, partially sectioned view of the bladder drain showing the manner in which the fluid collection tube 24 is joined to the proximal end of the grooved drainage member 12. The proximal end 14 of the drainage member 12 is provided with a narrowed neck 46 which is followed by an expanded end portion 48. The fluid collection tube 26 has a complimentary profile 50 adapted to snap over the end portion 48 to occupy the narrowed neck 46. Urine passing along the channels 20 between the internal wall of the urethra and the drain is channeled into the lumen of the collection tube 26 to flow out its proximal end 28, either continuously when the embodiment of Figure 1 is employed or in a controlled manner when the embodiment of Figures 2 or 8 is utilized. Detachment of the flexible plastic collection tube 26 may be accomplished by pulling on the tube 26 in the proximal direction while simultaneously employing a stabilizing push rod 52 to hold the drainage segment 12 in place. After detachment of the collection tube 26, the drain device is entirely contained within the urethral tract.

[0030] Figure 9(a) is an enlarged, exploded, partial sectional view of a drain member 12 having straight (non-spiral) grooves such as is illustrated in Figure 7 of the drawings and illustrating an alternative arrangement for connecting the drain body to an associated collection tube. The drain body 12 is molded or extruded so as to have a plurality of straight parallel grooves as best seen in Figure 7. Surrounding the proximal end portion of the

drain 12 is a ring member 53 which is secured to the exterior of the lobes of the drain body separated from one another by adjacent grooves. To better concentrate and direct the urine stream, the central portion of the drain body is cored out, leaving only the lobes depending in a zone of a predetermined length distal of the ring 53. The collection tube 24 includes an internal annular groove 55 into which the ring 53 on the drain body is adapted to be inserted. As such, the portion of the lobes on the drain body that are free from the central or core portion thereof fall within the lumen 57 of the collection tube and thereby directing the urine stream flowing down the longitudinal grooves in the drain body to flow into the lumen 57 of the collection tube.

[0031] To enhance the ability of the urine to find its way into the central lumen of the collection tube, it may be expedient to include a pattern of holes as at 59 through the wall of the collection tube where the size of the holes 59 are made slightly larger toward the distal end of the collection tube 24 and of a smaller size as at 61 at locations more proximal than the larger holes 51.

[0032] As those skilled in the art will appreciate from the foregoing description of the embodiment of Figure 9, the same technique for detaching the plastic collection tube 26 from the drainage device 12 can be utilized with the embodiment of Figure 9(a).

[0033] To assist in preventing migration of the drain devices having linear channels as in Figures 4 through 7, a series of longitudinally spaced rings as at 54 in Figure 10 may be placed about the drain body 12 at predetermined intervals. The rings are preferably relatively flat and are appropriately bonded to the drain body 12. It is found that the tissue of the inner wall of the urethra invaginates the channels 40, 42 on opposite sides of the rings 54, inhibiting longitudinal displacement of the drain assembly. With no limitation intended, the rings 54 may be approximately 2 mm wide and 1 mm thick. Further, they may be placed approximately 1 cm apart from one another along the length of the drain body 12 on one or both sides of any smooth segment of reduced diameter as at 32 in Figure 2 that is intended to cooperate with the urinary sphincter. By providing rings 54 along the length of the drain device, it is no longer necessary to include a central stylet receiving lumen 18. The stylet, instead, can be routed up one of the surface channels 40 and 42 and will be constrained by the rings.

[0034] Figure 11 shows an alternative anchoring arrangement to that shown in Figure 10. Instead of incorporating spaced-apart rings extending about the drain body, small, laterally projecting tines 56 that are located proximate the junction between the drain body 12 and the collection tube 24'. The tines 56 are intended to engage the interior wall of the urethra to prevent migration of the drain assembly in the distal direction toward the urinary bladder. When it is desired to remove the drain, a force applied to the strand 25 (Figure 1) will cause the tines 56 to deflect or collapse into alignment with the wall of the tubular body 12 and offer practically no drag or resistance against movement in the proximal direction. While the tines 56 are shown as being formed by cutting or slicing into the elastomeric material comprising the drain body 12, such tines can alternatively be provided on the collection tube 24'. Furthermore, rather than providing tines as at 56 in Figure 11, the retention means can take the form of a bulbous protrusion (not shown) formed on the lobes of the drain body 12.

[0035] Figures 12 through 14 show the configuration of an alternative device insertable into the female urethra for addressing stress incontinence. It is seen to comprise an elongated, flexible, plastic rod which, in the instant embodiments, is free from surface channels throughout its length. Preformed at its upper end is a retention segment 60 which is intended for placement within the urinary bladder. Such placement is enhanced by inserting a suitable stylet through an aperture 62 for temporarily straightening the curl of the retention segment 60 and allowing its insertion into the urethral opening. When the device 58 has been advanced sufficiently far up the urethra such that the segment of the device forming the retention member 60 resides in the urinary bladder, upon removal of the stylet, the memory property of the plastic material comprising the device 58 allows the retention member to reform into a flat spiral shape as illustrated.

[0036] To prevent the upward migration of the device as it is being worn, it is also provided with a proximal retention segment 64 which, in Figure 12, also comprises a flat ring-like segment that lies in a plane that is at a predetermined angle to the body portion 66 and that is dimensioned to abut the vestibule and underlie the labia minora. As such, the device may remain within the patient while still allowing normal sexual activity to take place.

[0037] Instead of forming the proximal end portion of the drain member 66 into a flat spiral such as is shown at 60 in Figure 12, to create a retention member, it is also contemplated that a separate closed ring as at 64 positioned about the drain body and secured to it by connecting spokes made from a suitable soft plastic be used. This is the configuration illustrated in Figure 12.

[0038] It has been found expedient to preform the device 58 so that the elongated straight segment 66 extends downward below the lower retention member 64 as indicated by numeral 68 in Figure 12. Urine flow tends to follow the straight portion 66 due to surface tension effects and provides a proper urine stream leaving the urethra.

[0039] The embodiment of Figure 13 is like that of Figure 12 except that the proximal retention ring 64 of Figure 12 is replaced by a highly flexible oval-shaped sheet of plastic 70 that is permeable to the flow of air, due to the fenestrated nature of the plastic material shown as a having a pattern of closely spaced openings, as at 72, extending through the thickness dimension thereof. Again, the air pervious retention member disk 70 is sized and shaped to conform to the area of the body closely

surrounding the urethral opening in the vestibule. The proximal end of the body member 66 extends below the retention member 70 and is supported by webs, as at 73, extending across a larger circular opening formed in the sheet 70 which permits urine to flow in a stream as it exits the device.

[0040] In the embodiment of Figure 13, measures are taken to decrease the weight of the retention member 60. Here, the curl portion only is made tubular and is fenestrated by a plurality of openings 61 extending through the wall of the curl to the lumen thereof. This minimizes trauma to the bladder.

[0041] Referring next to Figure 14, the incontinence control device 58 may include an appropriately sized cuff member 74 placed on and affixed to the straight shaft portion 66 of the device of Figures 12 and 13 at a location that will conform to the shape of the urethra proximate the woman's urinary sphincter. A urologist, fitting the woman with the device, will determine the appropriate size and shape of the cuff member 74 that will cooperate with the sphincter muscle to provide an effective seal when the sphincter is contracted. The cuff 74 may include a longitudinal bore sized so that the plastic rod 66 comprising the device and its retention member 60 can pass through that bore. Alternatively, the cuff member 74 may be provided with a fine slit extending through a side wall surface thereof to a central bore, allowing it to be assembled onto the device 58 by first spreading the cuff member and fitting it over the straight segment 66. Releasing the cuff member allows it to close about the shaft 66.

[0042] Figures 15a, b and c illustrate alternative shapes for the cuff member 74 from which the urologist may choose in deciding which provides the best seal with the urethra when the urinary sphincter is contracted. The cuff of Figure 15a is generally cylindrical but has conically tapered opposed ends to facilitate its being inserted and removed from the urethra along with the device 58. Figure 15b is somewhat bone-shaped where the sphincter cooperates primarily with the narrowed zone between the two larger opposed end portions. The cuff of Figure 15c has multiple annular narrowed regions which can assist deficient sphincter muscles to better coapt the urethral wall to the cuff during a sudden increase in bladder pressure occasioned by laughter, coughing or sneezing.

[0043] In any of the disclosed embodiments, it may prove efficacious to coat the drain member with hydrogel to render it more soft and lubricious to aid in insertion thereof. The coating may also incorporate a slow-release drug therein to combat urinary infection or to provide treatment to urinary organs.

[0044] This invention has been described herein in considerable detail in order to comply with the Patent Statutes and to provide those skilled in the art with the information needed to apply the novel principles and to construct and use such specialized components as are required. However, it is to be understood that the invention can be carried out by specifically different equipment and devices, and that various modifications, both as to the equipment details and operating procedures, can be accomplished without departing from the scope of the invention itself.

Claims

1. A flexible, self-cleaning urethral drain for draining of urine and fluid from the bladder through the urethra of a patient comprising:

   (a) a flexible, elongated drain body having a distal end and a proximal end with an outer diameter allowing passage through the urethra;
   (b) bladder retention means located adjacent to the distal end of the drain body for retaining the drain body in place in the urethra;
   (c) the drain body having an exterior surface with an open fluid drainage channel on said exterior surface cooperating with the wall of the urethra for draining urine between the exterior surface of the drain body and the urethral wall; and
   (d) means on the drain body for inhibiting longitudinal migration of said drain body relative to the urethral wall.

2. A flexible, self-cleaning urethral drain as in Claim 1 wherein the drain body includes an integrally formed longitudinal segment of a uniform diameter which is less than the outer diameter of the drain body and located along the drain body to cooperate with the external urethral sphincter in the patient for providing continence when the sphincter is normally contracted, and allowing passage of urine along the at least one channel when the sphincter is relaxed.

3. A flexible, self-cleaning urethral drain as in Claim 1 and further including a positionable sleeve member having a smooth exterior surface void of grooves and an interior surface conforming to the exterior surface of the drain body, including the at least one open fluid drainage channel.

4. The flexible, self-cleaning urethral drain as in Claim 1 wherein the inhibiting means comprises a plurality of longitudinally spaced ring members disposed on the drain body and overlaying the open fluid drainage channel.

5. The flexible, self-cleaning urethral drain as in Claim 1 wherein the inhibiting means comprises a plurality of integrally formed tines extending laterally of the exterior surface.

6. The flexible, self-cleaning urethral drain as in Claim

1 and further including a positionable sleeve member having a smooth exterior surface void of grooves and an interior surface conforming to the exterior surface of the drain body.

7. The flexible, self-cleaning urethral drain as in Claim 2 wherein the length of the longitudinal segment is between approximately 0.5 cm to 5.0 cm.

8. The flexible, self-cleaning urethral drain as in Claim 4 wherein the positionable sleeve member has a length between approximately 0.5 cm and 5.0 cm.

9. The flexible, self-cleaning urethral drain as in Claim 2 wherein the outer diameter of the longitudinal segment is between approximately 0.1 to 1.0 cm.

10. The flexible, self-cleaning urethral drain as in Claim 3 wherein the outer diameter of the positionable sleeve is in the range of from 0.3 cm. to 2.0 cm.

11. The flexible, self-cleaning urethral drain as in Claim 2 wherein the drain body tapers to the diameter of the longitudinal segment at a distal end of the longitudinal segment.

12. A flexible, self-cleaning urethral drain as in Claim 2 wherein a segment of the drain body proximal to the longitudinal segment joins to the longitudinal segment to form a squared shoulder.

13. The flexible, self-cleaning urethral drain as in Claim 1 wherein the bladder retention means comprises a curl at the distal end of the flexible drain body.

14. The flexible, self-cleaning urethral drain as in Claim 11 wherein the means for preventing migration of the drain body toward the bladder is affixed to said drain body at said proximal end.

15. The flexible, self-cleaning urethral drain as in Claim 14 wherein the migration preventing means comprises a ring disposed about the drain body at the proximal end and a plurality of flexible spoke members connecting the ring to the drain body.

16. The flexible, self-cleaning urethral drain in Claim 1 wherein the bladder retention means comprises a curl at the distal end of the drain body and the migration preventing means comprise a flexible, elastomeric sheet of a predetermined shape configuration disposed proximate the proximal end of the drain body and conforming to the vestibule of a female patient without overlaying the vaginal opening and the clitoris of said female patient.

17. The flexible, self-cleaning urethral drain as in Claim 16 wherein said flexible elastomeric sheet is fenestrated to allow passage of air and other fluids therethrough.

18. The flexible, self-cleaning urethral drain as in Claim 16 wherein the flexible elastomeric sheet is located intermediate the distal end and proximal end of the drain body.

19. The flexible, self-cleaning urethral drain as in Claim 6 wherein said positionable member is generally cylindrical in shape.

20. the flexible, self-cleaning drain as in Claim 6 wherein said positionable sleeve member is of non-uniform cross-section along the length thereof.

21. The flexible, self-cleaning urethral drain as in Claim 11 wherein the at least one channel extends along at least a portion of said bladder retention means.

22. The flexible, self-cleaning urethral drain as in Claim 13 wherein the curl has a flat profile and extends generally perpendicular to a longitudinal axis of the remainder of the drain body when installed in the bladder of the patient.

23. The flexible, self-cleaning urethral drain as in Claim 13 wherein the tubular body includes a stylet receiving lumen and the curl is preformed and can be reversibly straightened by inserting a stiffening stylet in the stylet-receiving lumen.

24. The flexible, self-cleaning urethral drain as in Claim 1 wherein the bladder retention means comprises an inflatable member.

25. The flexible, self-cleaning urethral drain as in Claim 1 wherein the drain body comprises a flexible polymer material selected from the group consisting of silicone, silastic, polyurethane and polyethylene.

26. The flexible, self-cleaning urethral drain as in Claim 25 wherein the polymer material has a durometer in the range of from 30 to 95 shore A.

27. The flexible, self-cleaning urethral drain for draining of urine and fluid from the bladder through the urethra of a patient comprising:

flexible, elongated drain body having a distal end and a proximal end with an outer diameter allowing passage through the urethra, said drain body including a curled segment proximate said distal end for retaining the drain body in place in the urethra, the drain body having an exterior surface adapted to cooperate with the wall of the urethra for draining urine and other fluids between the drain body and the ure-

thral wall.

28. The flexible, self-cleaning urethral drain as in Claim 27 wherein the curled segment comprises a tube having a wall defining a lumen and a plurality of openings formed through the wall and communicating with the lumen.

29. A flexible, self-cleaning urethral drain for draining of urine and fluid from the bladder through the urethra of a patient comprising:

(a) a flexible, elongated drain body having a distal end and a proximal end and a generally solid core, the drain body having an outer diameter allowing passage through the urethra;
(b) bladder retention means located adjacent to the distal end of the drain body for retaining the drain body in place in the urethra; and
(c) the drain body having at least one open fluid drainage channel on an exterior surface thereof of a depth sufficient for draining urine between the exterior surface of the drain body and the urethral wall.

30. The flexible, self-cleaning urethral drain as in Claim 29 and further including a tubular collection segment affixed to the proximal end of the drain body, the tubular collection segment having an internal lumen in fluid communication with the at least one channel for receiving urine from the at least one channel of the drain body, the collection segment terminating at a proximal end external to the urethra.

31. A flexible, self-cleaning urethral drain as in Claim 29 wherein the drain body includes an integrally formed longitudinal segment of a uniform diameter which is less than the outer diameter of the drain body and located along the drain body to cooperate with the external urethral sphincter in the patient for providing continence when the sphincter is normally contracted, and allowing passage of urine along the at least one channel when the sphincter is relaxed.

32. A flexible, self-cleaning urethral drain as in Claim 29 and further including a positionable sleeve member having a smooth exterior surface void of grooves and an interior surface conforming to the exterior surface of the drain body, including the at least one open fluid drainage channel.

33. The flexible, self-cleaning urethral drain as in Claim 31 wherein the length of the longitudinal segment is between approximately 0.5 cm to 3.5 cm.

34. The flexible, self-cleaning urethral drain as in Claim 32 wherein the positionable sleeve member has a length between approximately 0.5 cm and 3.5 cm.

35. The flexible, self-cleaning urethral drain as in Claim 31 wherein the outer diameter of the longitudinal segment is between approximately 0.1 to 1.0 cm.

36. The flexible, self-cleaning urethral drain as in Claim 32 wherein the outer diameter of the positionable sleeve is in the range of from 0.3 cm. to 1.0 cm.

37. The flexible, self-cleaning urethral drain as in Claim 31 wherein the drain body tapers to the diameter of the longitudinal segment at a distal end of the longitudinal segment.

38. A flexible, self-cleaning urethral drain as in Claim 31 wherein a segment of the drain body proximal to the longitudinal segment joins to the longitudinal segment to form a squared shoulder.

39. The flexible, self-cleaning urethral drain as in Claim 20 wherein the bladder retention means comprises a curl at the distal end of the flexible drain body.

40. The flexible, self-cleaning urethral drain as in claim 39 wherein the at least one channel extends along at least a portion of said curl.

41. The flexible, self-cleaning urethral drain as in Claim 39 wherein the curl has a flat profile and extends perpendicular to a longitudinal axis of the remainder of the drain body.

42. The flexible, self-cleaning urethral drain as in Claim 39 wherein the tubular body includes a stylet receiving lumen and the curl is preformed and can be reversibly straightened by inserting a stiffening stylet in the stylet-receiving lumen.

43. The flexible, self-cleaning urethral drain as in Claim 29 wherein the bladder retention means comprises an inflatable member.

44. The flexible, self-cleaning urethral drain as in Claim 29 wherein the drain body comprises a flexible polymer material selected from the group including silicone, silastic, polyurethane and polyethylene.

45. The flexible, self-cleaning urethral drain as in Claim 44 wherein the polymer material has a durometer in the range of from 30 to 95 shore A.

46. A method for treating urinary incontinence problems, comprising the steps of:

(a) inserting an elongated, flexible drain member having a proximal end and a distal end through the urethra of a patient such that the

distal end extends beyond the patient's urinary sphincter into the bladder, the drain member having at least one open fluid drainage channel formed in an exterior surface thereof through which urine can flow; and
(b) affixing a urine collection tube to the proximal end of the drain member.

47. A method for treating urinary incontinence problems comprising the step of:

(a) inserting an elongated, flexible drain member having a proximal end and a distal end through the urethra of a patient such that the distal end extends beyond the patient's urinary sphincter into the bladder, the drain member having at least one open, fluid drainage channel formed in an exterior surface thereof through which urine can flow and a longitudinal segment having a smooth exterior surface of a predetermined diameter and void of said at least one channel located such that when the distal end if disposed in the bladder, the segment is in lateral alignment with the urinary sphincter.

48. The method as in Claim 47 and further including the step of:

(a) affixing a urine collection tube to the proximal end of the drain member.

49. A method for controlling urine flow in a patient, comprising the steps of:

(a) inserting an elongated, flexible drain member having a proximal end and a distal end through the urethra of a patient such that the distal end extends beyond the patient's urinary sphincter into the bladder and with the proximal end extending outward through the urethral opening.

50. The method as in Claim 49 and further including the step of affixing a cuff member of a predetermined outer dimensional onto the drain member at a location surrounded by the urinary sphincter.

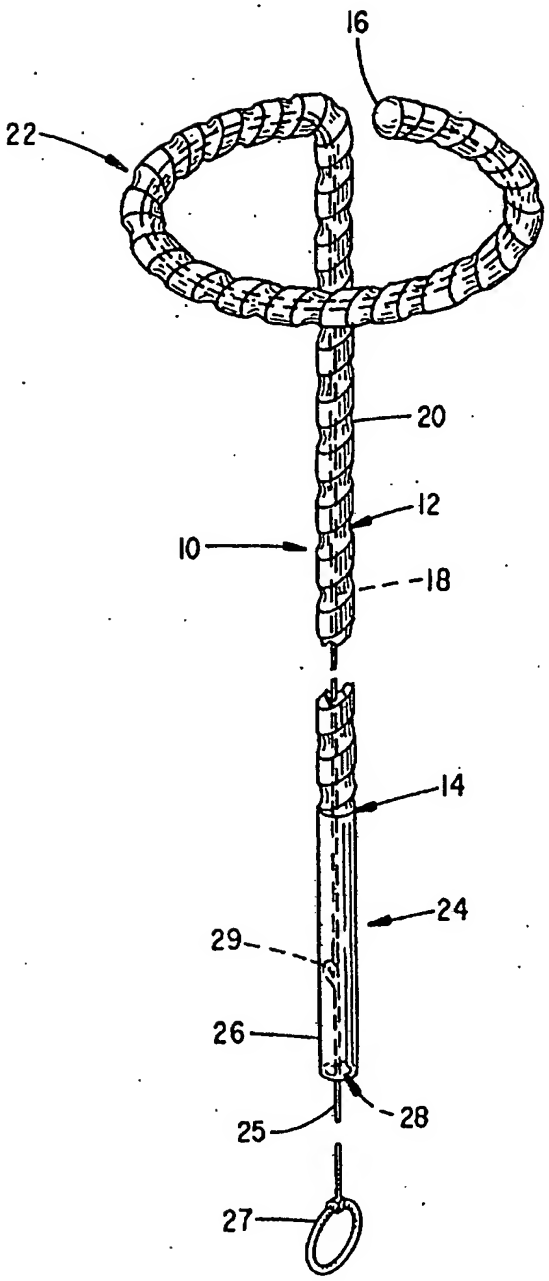


FIG. 1.

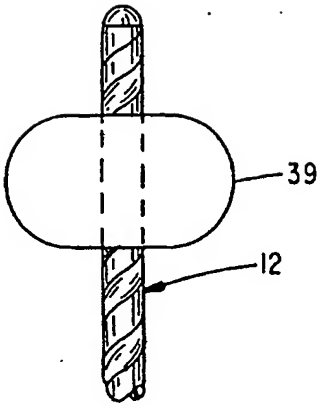


FIG. 1 (a)

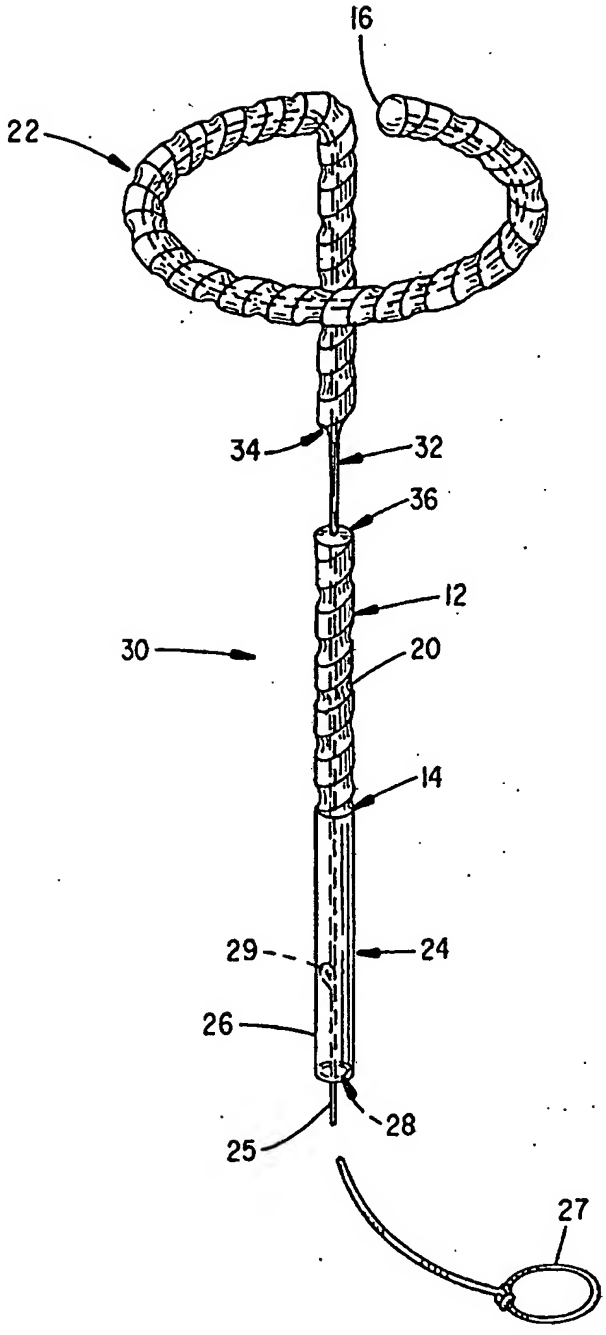


FIG. 2

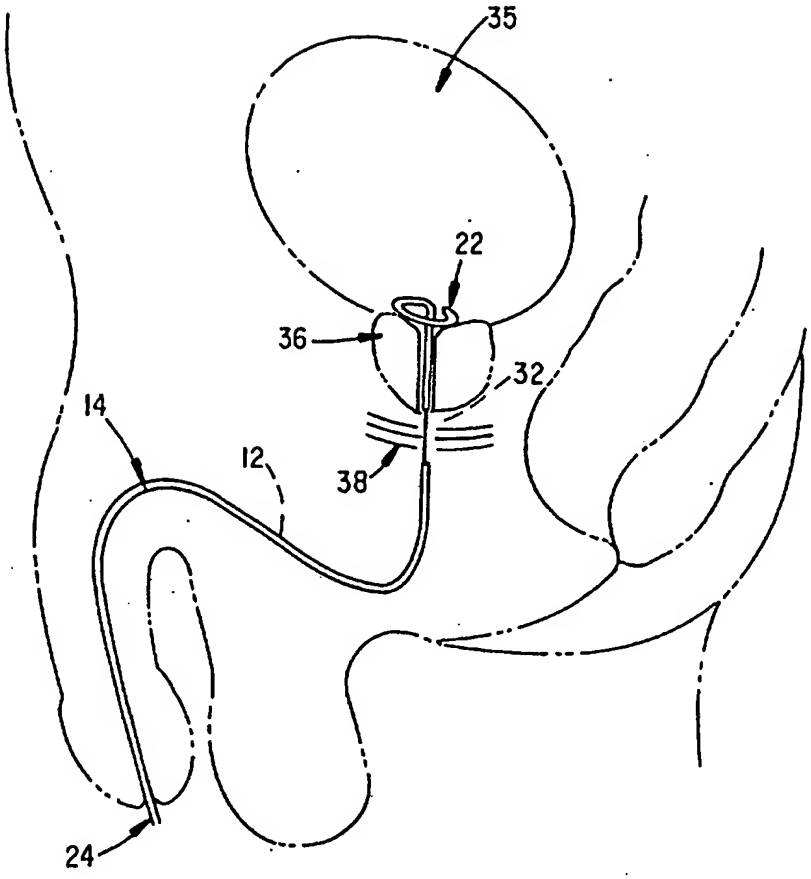


FIG. 3

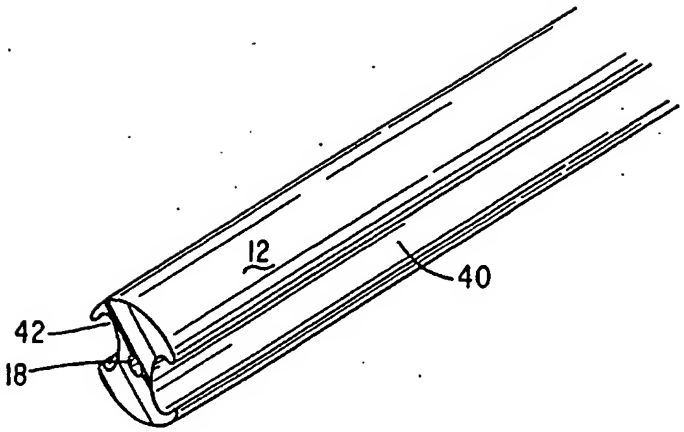


FIG. 4

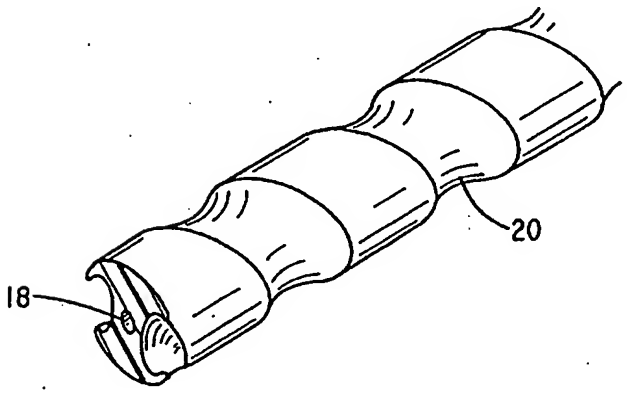


FIG. 5

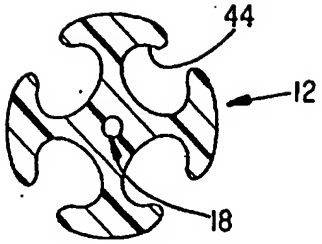


FIG. 6

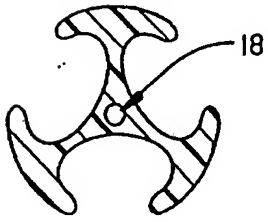


FIG. 7

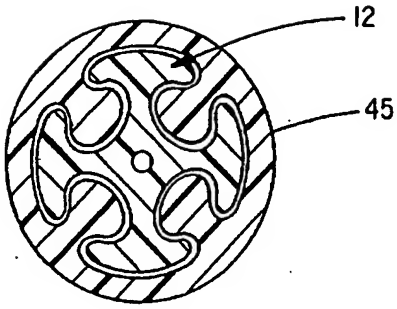


FIG. 8

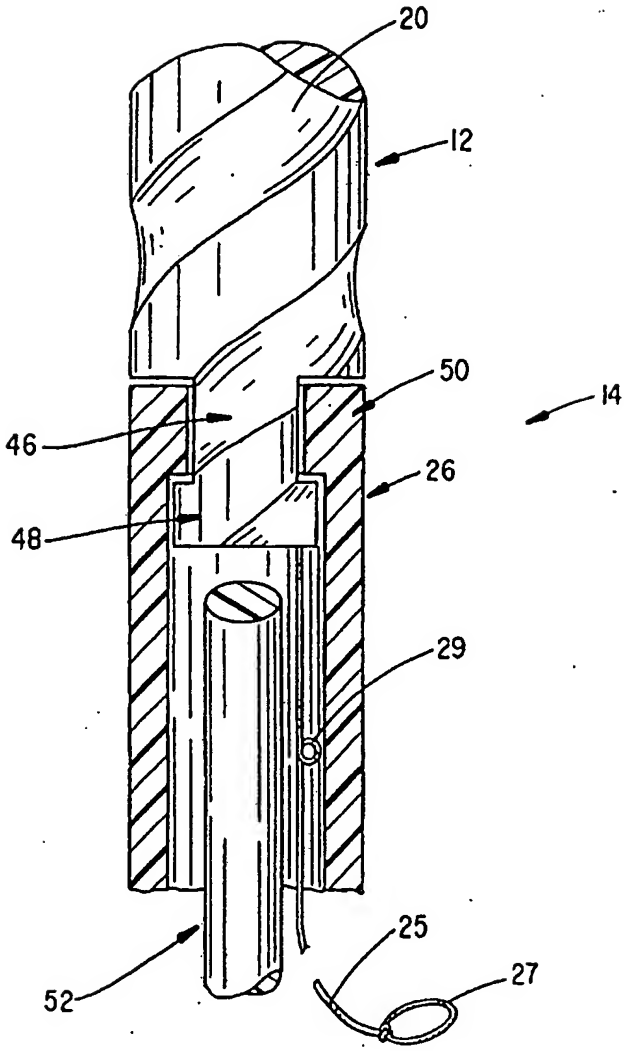


FIG. 9

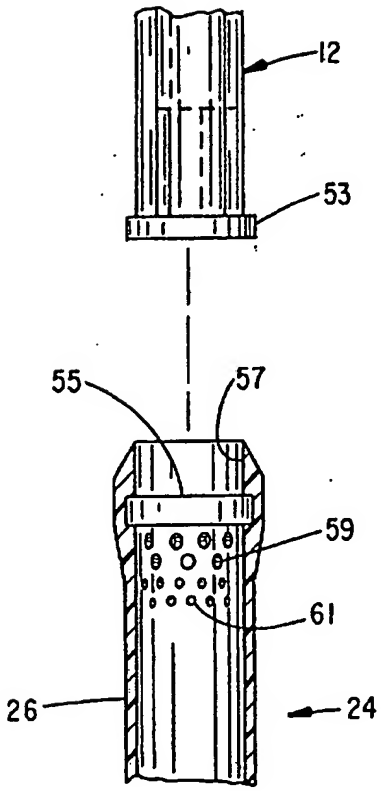


FIG. 9 (a)

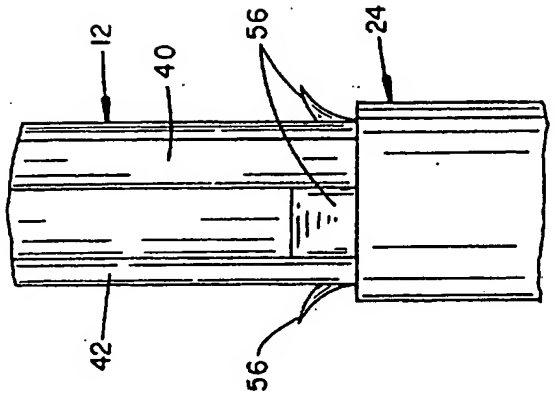


FIG. 11

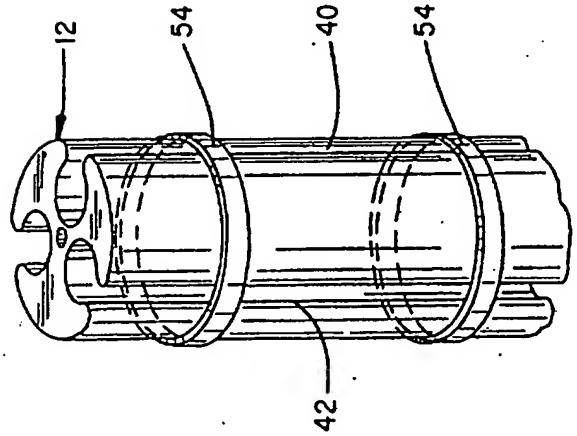


FIG. 10

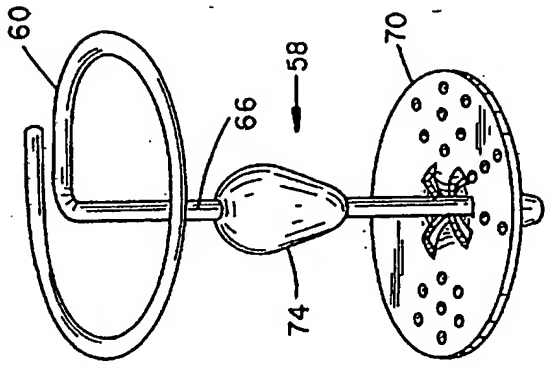


FIG. 14

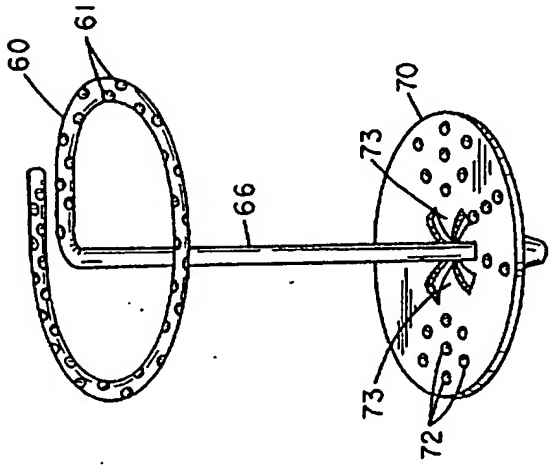


FIG. 13

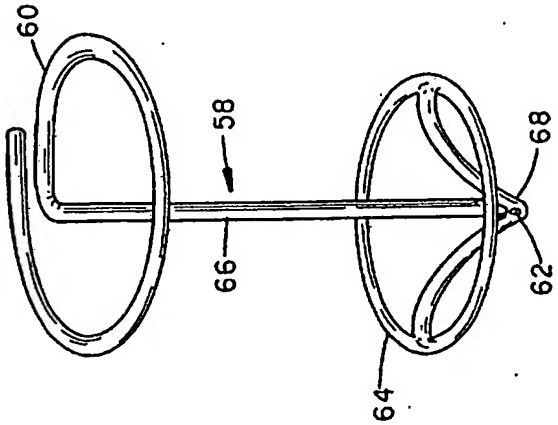


FIG. 12

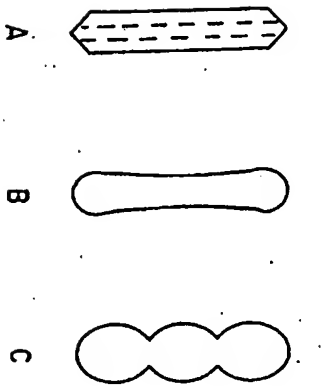


FIG. 15

BG

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/00 — A2

(11) International Publication Number: WO 96/01597

(43) International Publication Date: 25 January 1996 (25.01.96)

(21) International Application Number: PCT/US95/07777

(22) International Filing Date: 19 June 1995 (19.06.95)

(30) Priority Data:
08/273,418 11 July 1994 (11.07.94) US

(71) Applicant: DACOMED CORPORATION [US/US]; Suite 17, 1701 E. 79th Street, Minneapolis, MN 55425-1152 (US).

(72) Inventor: TIMM, Gerald, W.; 1620 Mount Curve Avenue, Minneapolis, MN 55403 (US).

(74) Agent: SCHUMANN, Michael, D.; Merchant, Gould, Smith, Edell, Welter & Schmidt, 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402 (US).

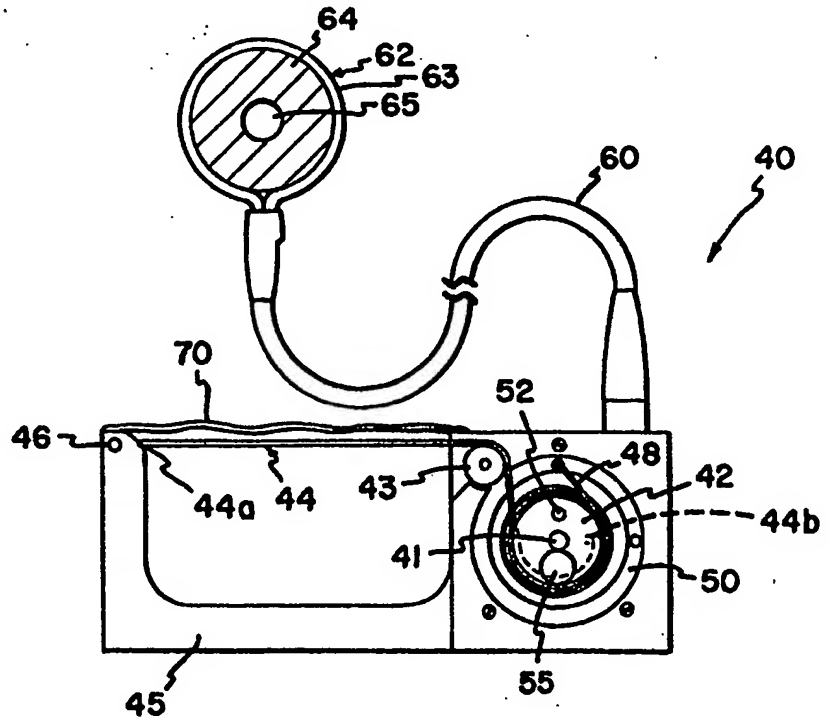
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: VESSEL OCCLUSIVE PROSTHESIS

(57) Abstract

The present invention relates to a vessel occlusive apparatus for reversibly occluding a fluid conveying vessel in a human and/or animal. In one embodiment the vessel occlusive apparatus comprises an elongated member at least partially encircling the vessel, and means connected to the elongated member for applying tension to the elongated whereby pressure is applied to the vessel to prevent fluid from passing therethrough.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

VESSEL OCCLUSIVE PROSTHESIS

Background of the Invention

The present invention relates to an apparatus and method for occluding fluid conveying vessels in the body. In particular, the invention relates to an apparatus and method for occluding the urethra so as to restore urinary continence to patients with urinary control problems.

Urinary incontinence is a frequent and distressing sequel to various neurological diseases, surgical procedures, spinal cord injury, etc. Various urethral occlusive apparatus have been developed in an effort to restore urinary continence to patients with urinary control problems.

In particular, apparatus utilizing hydraulic sphincters or cuffs have been used to provide urethral occlusion. See for example:

Timm, G.W., Merrill, D.E. and Bradley, W.E. "Intermittent Occlusion System", IEEE Transactions On Bio-Medical Engineering, BME-17:352, 1970.

Timm, G.W., "An Implantable Incontinence Device", J. Biomechanics, 4:213-219, 1971.

U.S. Patent No. 3,744,063; issued July 10, 1973.

U.S. Patent No. 3,863,622; issued February 4, 1975.

U.S. Patent No. 4,571,749; issued February 25, 1986.

U.S. Patent No. 4,731,083; issued March 15, 1988.

U.S. Patent No. 4,784,660; issued November 15, 1988.

One particular problem with hydraulic sphincters or cuffs is that they often do not apply uniform pressure on the urethra. As the cuff or sphincter is inflated it folds or changes its shape, often in a non-uniform manner, thereby exerting uneven occlusion force on the urethra. This can result in urethral erosion or urethra tissue being worn away after extensive use.

Another approach to treating urinary incontinence is to surgically adjust the angle between the urethra and the bladder. This angle is often referred to as the angle of

the urethro vesical junction. Of course a problem with this procedure is that the effects of the surgery cannot be readily changed and requires trained medical professionals to do so.

The present invention offers a substantial improvement over existing urethral occlusive apparatus and methods.

Summary of the Invention

The present invention relates to an occlusive apparatus and method for reversibly occluding fluid conveying vessels in the body.

The present invention has numerous applications for controlling and/or occluding fluid flow in fluid conveying vessels in humans and/or animals. Its applications include control of fecal incontinence, venous outflow from a penus and thus impotence, bile duct flow, male and female fertility, blood flow in blood vessels, etc. The present invention can be used in conjunction with most any vessel in the body. In many applications the present invention will occlude the vessel as required to stop or prohibit fluid flow. In other applications the present invention will control the amount of fluid flow through the vessel.

One embodiment of the present invention relates to an occlusive apparatus and method for reversibly occluding the urethra of a patient.

In a preferred embodiment, the urethral occlusive apparatus and method includes an elongated member at least partially encircling the urethra. Means is connected to said elongated member for placing the elongated member under tension, whereby occlusive force is applied to the urethra to prevent fluid from passing through.

In one embodiment, the elongated member substantial surrounds the circumferential extent of the urethra so as to form an annulus about the urethra. When the elongated

member is placed under tension, the diameter of the annulus is reduced thereby exerting a radially inward directed force which occludes the urethra.

In yet another embodiment, the elongated member only partially surrounds the circumference of the urethra. When the elongated member is placed under tension, the elongated member exerts, at least in part a lateral bending force on the urethra so as to change the angle of the urethra thereby occluding the urethra.

In one embodiment of the present invention the elongated member is partially enclosed in a flexible sheath. The sheath shields the elongated member from the urethra. Preferably the sheath is made from a material which has little or no folding occur as the elongated member is tensioned.

In a preferred embodiment of the invention the sheath is made of expanded polytetrofloraethylene (expanded PTFE).

In one embodiment, the elongated member is partially, slidably disposed in a substantially non-compressible tube. The sheath is suitably attached proximate at least one end of the sheath to the tube. If the elongated member forms an annulus about the urethra, the sheath is suitable connected at both ends of the sheath to the tube. Accordingly as the elongated member is tensioned or pulled, the length of the sheath contracts thereby exerting force on the urethra.

In one embodiment a pulley and spring assembly is used to tension the elongated member. In still one embodiment, the pulley assembly is manually activated, and in yet another embodiment the pulley is motor driven.

In one embodiment the pulley assembly includes two pulleys mounted for pivotal movement about a common axis. The two pulleys are interconnected by a coiled spring which serves as a shock absorber to take up any slack in the system and to absorb excessive force or resistance encountered during operation thereby resulting in smoother

operation of the apparatus. The spring additionally keeps the elongated member in tension which thereby creates a preset occlusive force around the urethra.

In yet another embodiment, the present invention pertains to an electro-mechanical apparatus and method for exerting an urethral occlusive force which utilizes an abdominal pressure sensor providing input signals representative of the extravesical, abdominal pressure to an electronic controller which controls the tension of the elongated member in response to the input signals received from the pressure sensor.

A preferred embodiment of the present invention is totally implantable in the body of the patient.

In yet another embodiment, the implantable apparatus requires no tubes, wires, or other external control mechanisms passing through the skin of the patient.

An advantage of one embodiment of the present invention is that it does not use a hydraulic cuff or sphincter mechanism. As a result it is able to apply a more uniform radial force against the circumference of the urethra when occluding the urethra.

These and various other features and advantages of novelty which characterize the invention are pointed out with particularity in the claims annexed hereto and forming a part hereof. However, for a better understanding of the invention, its advantages and objects obtained by its use, reference should be had to the drawings which form a further part hereof, and to the accompanying descriptive matter, in which there is illustrated and described a preferred embodiment of the invention.

Brief Description of the Drawings

In the drawings in which like reference numerals and letters generally indicate corresponding parts throughout the several views;

Figure 1 is a side elevational view in partial cross-section illustrating an embodiment of a urethral occlusive apparatus in accordance with the principles of the present invention;

Figure 2 is a side elevational view of the embodiment shown in Figure 1 with the occlusive device activated so as to occlude the urethra;

Figure 3 is an exploded view of the embodiment shown in Figures 1 and 2;

Figure 4 is a diagrammatic view of an alternative embodiment of the present invention including a drive motor;

Figures 5A,B are diagrammatic views of still another embodiment of a urethral occlusive apparatus which has a distal end of an elongated member anchored to bone on one side of the urethra, the elongated member being slidable in an outer sleeve member which is attached to bone on the other side of the urethra; and

Figures 6A,B are diagrammatic views showing the embodiment of Figures 5A,B interacting with the urethra;

Figure 7 is a diagrammatic view of still another embodiment of a urethral occlusive apparatus including a controller and pressure sensor for automated operation.

Detailed Description of Preferred Embodiment(s)

As noted above, the apparatus and method of the present invention might be utilized in conjunction with any number of different vessels in humans and animals which are used to convey fluid. The following are some examples of various applications of the present invention; however, this list is by no means exhaustive of the numerous applications in which the present invention may be used. The present invention might be used to control fecal incontinence or bowl movements, to control venous outflow from a penis and thus impotence, to control bile

duct flow, to control fluid flow in the vas deferens and thus male fertility, to control fluid flow in the fallopian tubes and thus control female fertility, to control blood flow in blood vessels for vascular studies or the like, etc.

The above noted applications are but a few of the many applications of the present invention. The presention invention will now be described more particularly in view of its application for occluding the urethra and thus controlling incontinence. It will be appreciated that the urethra is shown with only a single lumen or passageway. However, in many applications such as controlling venous outflow from the penis, there are multiple lumens which will be occluded by the present invention.

A urethral occlusive apparatus method in accordance with the present invention in the preferred embodiment is designed to be totally implantable. The apparatus has no tubes or wires or other electro-mechanical connection passing through the skin. Additionally, in the preferred embodiment no external appliances are required to operate the system. However, coupled coils might be used either for continuous powering of the device or to recharge batteries which are implanted to power the device. Preferably, the complete device is capable of being inserted using existing endoscopic or other minimally invasive techniques.

In the preferred embodiment, the urethral occlusive apparatus is made of materials and has a geometric configuration which is compatible with the body. In one embodiment, materials used might include titanium, stainless steel or implantable grade plastics, and the apparatus might have a dimension of 1 X 3 X 5 cm. In the preferred embodiment, all surfaces in contact with body fluids and/or tissue meet the required; e.g., class 6 U.S.P., tests for toxicity and pyrogenicity. In addition, the corners and edges are rounded and surfaces are

nonabrasive to body structures. The urethral apparatus of the preferred embodiment is also lightweight so as to minimize any chance for migration. One embodiment might weigh 100 grams.

In the preferred embodiment, the operation of the urethral apparatus is easily understood and readily controlled by the user requiring a minimal amount of manual or mental dexterity. Activation and/or deactivation shall be accomplished through the intact skin. The activation/deactivation mechanism of the urethral apparatus shall be of a size to be readily grasped by the user. In alternative embodiments the activation/deactivation device may be electro-magnetically controllable or controlled by other wireless means such as coupled coils or radio frequency (RF) signals. In yet other embodiments, a tensioning algorithm shall be modifiable from outside the body.

In the preferred embodiment, the occlusive force exerted against the urethra shall be sufficient to prevent urinary leakage but not so great the urethra viability is impaired. Preferably, the pressure shall not exceed 100 cm H2O for more than 10 minutes when in the activated state. Moreover, the urethral apparatus shall not interfere with urine flow when in the open or deactivated state.

Alternate embodiments of the urethral apparatus shall have automatic pressure release capabilities with high intravesical pressure. In one preferred embodiment, a detrusor muscle contraction (bladder muscle contraction) producing an intravesical pressure greater than 120 cm H2O (estimated normal voiding pressure) shall result in release of pressure against the urethra upon being sensed by an abdominal sensor present in the urethral apparatus.

Preferably, a nonfunctioning urethral apparatus shall leave the patient in his/her preimplant incontinent condition. The device shall be inert in the presence of body tissues, and materials contained within the urethral

apparatus shall be of an implantable quality and be nonallergenic to the patient. Preferably the mechanism will prevent leakage during coughing, straining or other sudden increases in abdominal pressure. A preferred embodiment of the system shall contain a sensor to be placed in the abdominal cavity to feed back tensioning information to the controller. The sensor senses intraabdominal, extravesical pressure that causes intravesical pressure (i.e. bladder pressure) to rise without a detrusor muscle contraction. When this occurs in the presence of impaired urinary sphincter contractibility, urinary incontinence occurs. The sensor could also sense neural impulses related to detrusor muscle activity and cause the urethral apparatus to respond appropriately.

Preferably materials used in the system shall not deteriorate in contact with body fluids and tissue or as to provide the urethral apparatus with long-term usage. In the preferred embodiment, the maximum activation pressure obtainable in the system shall be inherent and therefore not dependent upon the ability of the user to manipulate the device.

More particularly, there is illustrated in Figures 1-3, a preferred embodiment of the present invention, generally referred to by the referenced numeral 40. The urethral apparatus 40 includes a pulley 42 mounted for pivotal movement about an axial member 41 defining an axis of rotation. A member 44 extends over a guide pulley 43 and around the pulley 42. The member 44 is connected proximate a first end 44a to a housing 45 of the urethral apparatus 40 by a fastener 46. An opposite end 44b of the member 44 is suitably fastened to the pulley 42 in a groove formed in the pulley 42. In one embodiment the member 44 might be directly attached or attached after only a partial revolution to the pulley 42 and in still in another embodiment the member 44 might be wrapped around the pulley 42 one or more complete revolutions.

A coiled spring 48 is coaxially mounted about the pulley 42. A first end 48a of the coiled spring 48 is suitably fastened to the pulley 42 and a second end 48b is suitably fastened to a large diameter pulley 50 which is pivotable about the axis 41. A pin 52 biased axially by a coil spring 53 is alignable with a pin 54 upon rotation of the pulley 42 a predetermined distance in a clockwise direction. The pin 54 is slideably mounted in a housing portion 45a and has a push button 55 attached at the end of the pin 54. In the embodiment shown, the housing portion 45a is suitably mounted to the rest of the housing by fasteners 47. When the pin 52 is aligned with the pin 54, the pin 52 axially biases the pin 54 and projects into a bore of the housing 45a where the pin 54 is slideably disposed. The push button 55 can be used to force the pin 54 axially back toward the pin 52 such that the pin 52 is forced out of the bore of the housing 45a, whereby the pulley 42 is caused to rotate counter clockwise due to the tension in the spring 48.

A flexible elongated member such as a cable 58 is disposed in a hollow, axially non-compressible conduit 60 so as to be slidable therein. The cable 58 is preferably substantially non-elastic along its longitudinal axis so that exerting a force and causing movement of a first proximal end of the cable 58 will cause a corresponding movement of the cable 58 at a second distal end. A distal end portion of the cable 58 extends from an open end 61 of the conduit 60 and is looped back and suitably attached to the end of 61 of the conduit 60 so as to form an annulus 62 which can be positioned to surround a urethra 64. The distal end portion of the cable 58 is slidably enclosed within a sheath 63 which is suitably attached at its ends to the end 61 of the conduit 60. The sheath 63 shields the urethra from the cable 58 and forces against the urethra when the cable 58 is tensioned. In a preferred embodiment, the sheath 63 is made of expanded PTFE.

The conduit 60 is attached to and extends from the housing 45 which houses the pulleys 42,50. A proximal end of the cable 58 is suitably attached to the pulley 50. In the embodiment shown, the proximal end of the cable 58 has a cylinder member 66 suitably attached. The cylinder member 66 is suitably attached in a groove 67 of the pulley 50 by a set screw 68.

While the housing 45 is made of a relatively rigid biocompatible material, a top surface of the housing includes a resilient flexible membrane 70 which is inwardly deformable upon the application of a force so as to displace the member 44 as generally illustrated in Figure 2. It will be appreciated that this force might simply be applied by a user manually pressing against their skin adjacent the flexible membrane 70.

As illustrated in Figure 2, upon depressing down on the membrane 70 the member 44 is displaced so as to cause rotation of the pulley 42 which in turn causes rotation of the pulley 50 due to the coil spring 48 interconnecting the pulleys 42, 50. Rotation of the pulley 50 causes tensioning of the cable member 58. As shown in Figure 2, this results in a subsequent reduction in size of the annulus 62 formed by the cable 48 and the sheath 63, thereby exerting an occlusive force on the urethra 64 so as to close the urethral passage 65 and prevent any leakage.

In the embodiment shown, when the flexible membrane 70 is sufficiently depressed, the pulley 42 rotates the spring biased pin 52 into axial alignment with the pin 54 whereupon the spring biased pin 52 is received in an axial bore of the housing portion 45a where the pin 54 is slideably disposed. Accordingly, when this occurs, the pulleys 42,50 are locked in the activated state thereby maintaining tension on the cable 58 and occluding the urethra 64. To release the tension on the cable 58, the push button 55 is simply pressed from the side of the housing 54 such that the pin 54 forces the pin 52 out of

the bore of the housing portion 45a whereupon the pulley 42 is allowed to freely rotate thereby releasing or reducing the tension exerted on the cable 58. Accordingly, the annulus 62 is enlarged and the urethra 64 is no longer occluded.

Figure 4 is an alternative embodiment of the present invention wherein a motor 100 is provided. The motor 100 includes a pulley 102 mounted on a drive shaft 104 of the motor 100. The pulley 102 is suitably connected to the pulley 42 for rotating the pulley 42. In the embodiment shown, the pulley 102 is connected by an elongated member 106 which is suitably fastened to the drive pulley 102 and the pulley 42. Guide pulleys 108 are shown guiding the elongated member 106. It will be appreciated that the drive motor 100 is powered by a suitable power source interconnected by to the drive motor 100 by an electrical conduit 110. Varying tensions might be placed on the cable member 58 by using the motor 100. Moreover, the motor 100 will preferably include a brake mechanism for retaining the apparatus in an activated state. The drive motor might be activated manually or automatically activated according to certain predetermined conditions.

Shown in Figures 5A,B is yet another embodiment of the present invention wherein the cable member 58 and sheath 63 are attached proximate a distal end to a pubic bone structure 109 in the body on one side of the urethra 64. The sheath 63 is connected to the conduit 60 proximate a proximal end. The conduit 60 is in turn attached to the pubic bone structure 109 on the other side of the urethra 64. Accordingly, in this embodiment it is not necessary to form an annulus about the urethra. By tensioning or pulling on the cable member 58, the cable member 58 and the sheath 63 cooperate with the bone structure 109 to occlude the urethra 64. The cable 58 and sheath 63 combination exerts in part a lateral bending force on the urethra which bends or kinks the urethra thereby causing occlusion to occur. This is best shown in

Figures 6A,B where the urethra 64 and bladder 71 are illustrated. In Figure 6A the urethral device is shown in a relaxed or deactivated state, and in Figure 6B, the urethral device is shown in an activated or occlusive state.

Shown in Figure 7 is yet another embodiment of the present invention which includes a controller 120 electrically connected to an abdominal pressure sensor 122 and a power source 124. The controller 120 is implanted in the body and suitably connected to the motor 100 of the urethral apparatus 40 by the connection 110 for providing current to the motor 100. The pressure sensor 122 is placed in the prevesical space next to the urinary bladder to sense intraabdominal pressure and send signals representative of the pressure so sensed. Upon detection of a predetermined pressure by the pressure sensor 122, the urethral apparatus 40 is activated by the controller 120 according to a predetermined algorithm or preprogrammed logic. The algorithm provides for the tension in the cable to be relaxed when intraabdominal pressure is less than resting bladder pressure of approximately 20cm H20. When intraabdominal pressure exceeds 20cm H20, tension is applied proportionately until the maximum occlusive pressure at 100cm H20 is obtained. Cable tension is again released as the intraabdominal pressure drops. Accordingly, the cable is in a relaxed state most of the time, thereby further reducing the risk of urethral erosion.

The power source 124 might include batteries or externally supplied power. The controller 120 might include interface capability for interconnection to various peripherals including an adapter/charger which might be plugged into an AC outlet by a suitable power cord. The interconnection might be accomplished by coupled transformer coils or other suitable methods. This interconnection might also provide for external resetting and/or modification of the predetermined algorithm. Use

of interconnection methods such as coupled transformer coils will allow the interface to be accomplished preferably without the use of wires or other physical connectors extending through the skin. It will be appreciated that this embodiment will preferably include program logic which can be readily programmed for different parameter settings, functions, etc. both before implantation of the urethral apparatus 40 or after implantation.

Having read the foregoing description, it is to be understood, that even though numerous characteristics and advantages of various embodiments in accordance with the principles of the invention have been set forth in the foregoing description, together with details of the structure and function of the invention, the disclosure is illustrative only, and changes may be made in detail, especially matters of shape, size and arrangement of the parts within the principles of the invention to the full extent indicated by the broad general meaning of the term in which the appended claims are expressed.

WHAT IS CLAIMED IS:

1. An occlusive apparatus for reversibly occluding a fluid conveying vessel in the body, comprising:

an elongated member at least partially encircling the vessel; and

means connected to said elongated member for applying tension to the elongated member whereby pressure is applied to the vessel to prevent fluid from passing therethrough.

2. A method for controlling fluid flow in a fluid conveying body vessel, comprising the steps of:

encircling at least a portion of the urethra with an elongated member; and

applying tension to the elongated member so as to occlude the urethra.

3. A method in accordance with claim 2 for controlling fecal incontinence.

4. A method in accordance with claim 2 for controlling venous outflow from a penis.

5. A method in accordance with claim 2 for controlling bile duct fluid flow.

6. A method in accordance with claim 2 for controlling fluid flow in the vas deferens thereby providing male fertility control.

7. A method in accordance with claim 2 for controlling fluid flow in a fallopian tube thereby providing female fertility control.

8. A method in accordance with claim 2 for controlling fluid control in blood vessels.

9. A urethral occlusive apparatus for reversibly occluding the urethra of a patient, comprising:

an elongated member at least partially encircling the urethra; and

means connected to said elongated member for applying tension to the elongated member whereby pressure

is applied to the urethra to prevent fluid from passing therethrough.

10. The urethral occlusive apparatus of claim 9, further including a sensor for determining intraabdominal pressure and wherein said means for applying tension to the cable adjusts the tension on the cable in response to changing intraabdominal pressure.

11. The urethral occlusive apparatus of claim 9, wherein said elongated member forms an annulus about the urethra.

12. The urethral occlusive apparatus of claim 9, wherein said elongated member is partially enclosed in a sheath proximate a distal end portion, whereby said sheath forces against the urethra as the elongated member is tensioned.

13. The urethral occlusive apparatus of claim 12, wherein one end of the elongated member is connected to said means for applying tension, a proximal end portion of the elongated member slidably extends through a non-compressible conduit and the distal end portion of the elongated member extends beyond the conduit.

14. The urethral occlusive apparatus of claim 12, wherein said means for applying tension includes a constant force spring.

15. The urethral occlusive apparatus of claim 12, wherein said means for applying tension includes a torsion spring.

16. The urethral occlusive apparatus of claim 9, wherein said means for applying tension includes means to activate and deactivate said means for applying tension, said means to activate and deactivate being operable from outside the body.

17. The urethral occlusive apparatus of claim 10, wherein said means for applying tension adjusts tension applied to the elongated member to release pressure on the urethra if the intravesical pressure exceeds 120 cm of water.

18. The urethral occlusive apparatus of claim 9, further including a biocompatible, sheath slidably enclosing a distal end portion of the elongated member.

19. A urethral occlusive apparatus for reversibly occluding the urethra of a patient, comprising

an elongated member encircling the urethra so as to form an annulus about the urethra;

tension means connected to said elongated member for applying tension to the elongated member so as to vary the diameter of the annulus; and

actuating means connected to the tension means for activating and deactivating the urethral occlusive apparatus.

20. An apparatus in accordance with claim 19, wherein the actuating means is manually operable.

21. An apparatus in accordance with claim 19, wherein the actuating means is automatically operable.

22. An apparatus in accordance with claim 19, wherein urethral occlusive apparatus is configured and arranged for implantation in a human.

23. A method for controlling incontinence, comprising the steps of:

encircling at least a portion of the urethra with an elongated member; and

applying tension to the elongated member so as to occlude the urethra.

24. The method of claim 23 further comprising the step of sensing the intraabdominal pressure and adjusting the tension of the elongated member based on the pressure sensed.

25. An apparatus comprising:

a cable at least partially encircling the urethra;

abdominal pressure sensor sensing abdominal pressure; and

electro-mechanical tension controller controlling the tension applied to the cable in response

to the abdominal pressure sensed by the abdominal pressure sensor.

FIG. 1

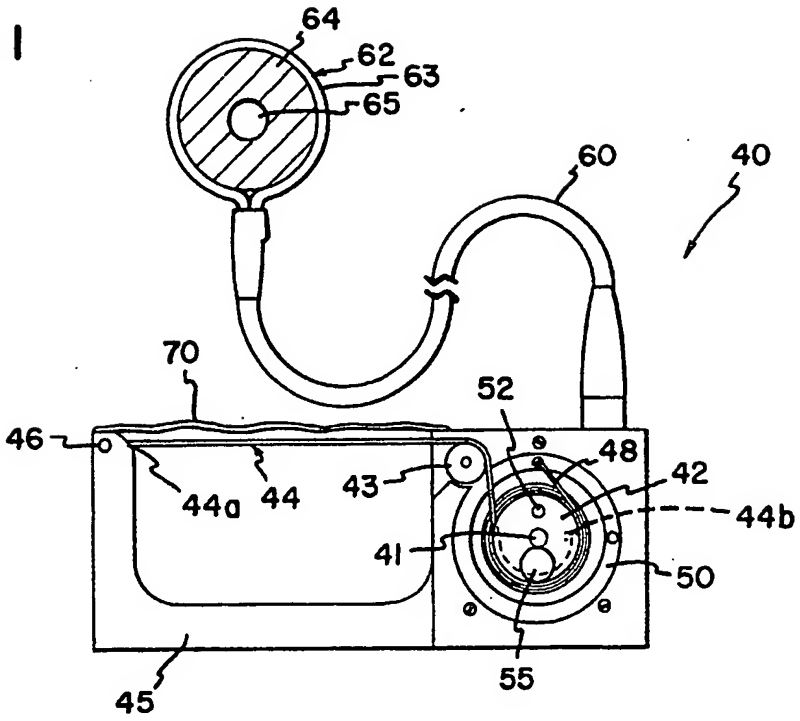
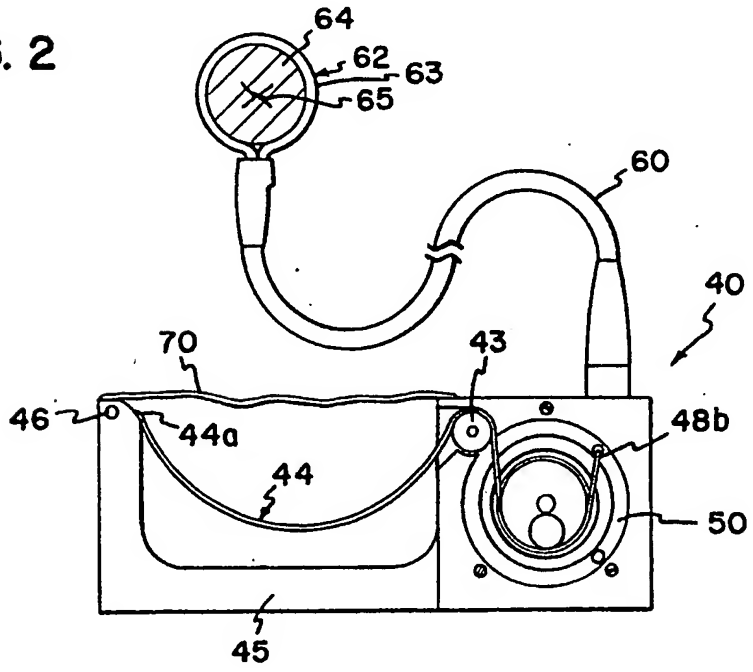

64
62
63
65
60
40
70
52
46
48
42
43
44a
44
44b
41
50
55
45

FIG. 2


64
62
63
65
60
40
70
43
46
48b
44a
44
50
45

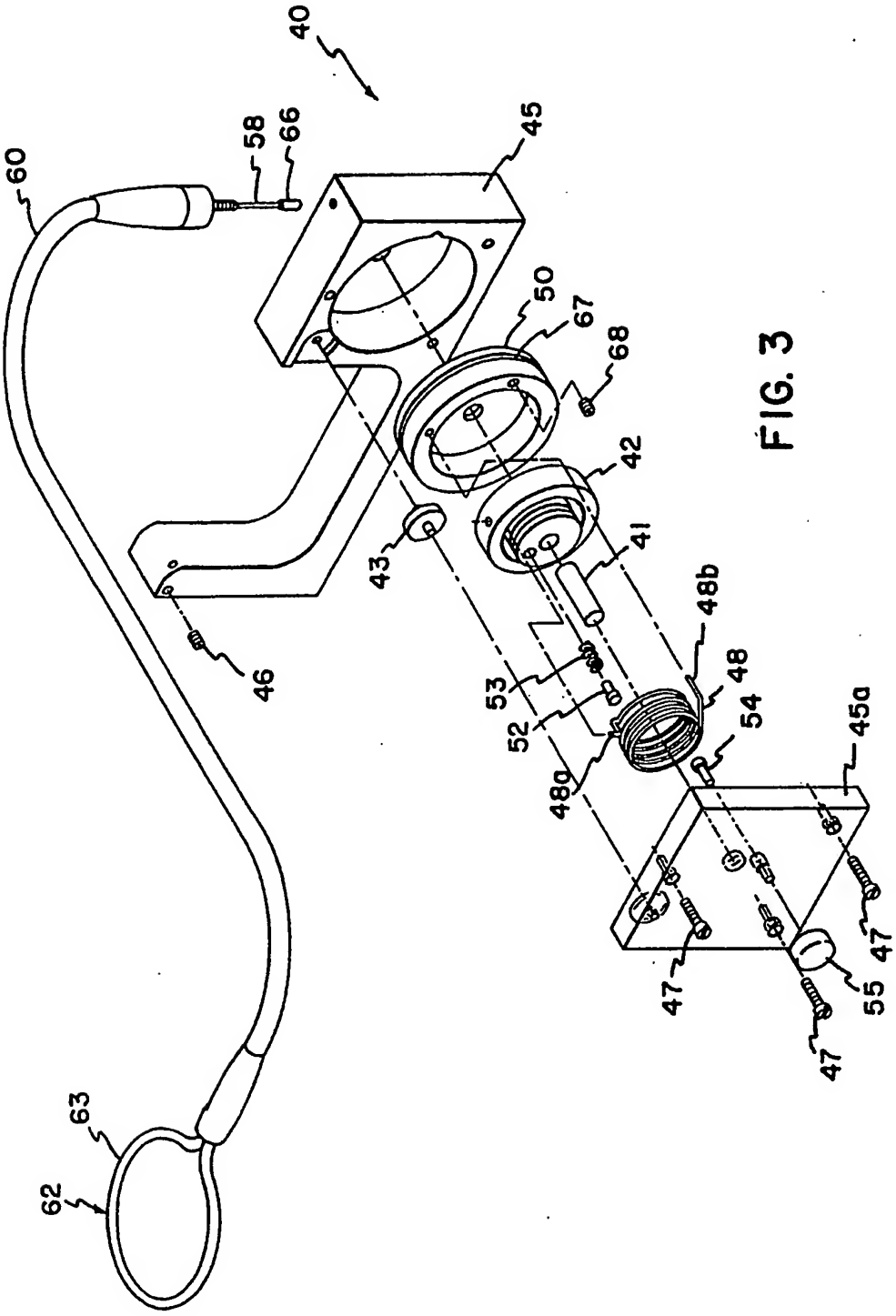

40
58
66
45
60
50
67
68
42
41
43
48b
46
53
48
52
54
45a
48a
47
47
55
47
63
62

FIG. 3

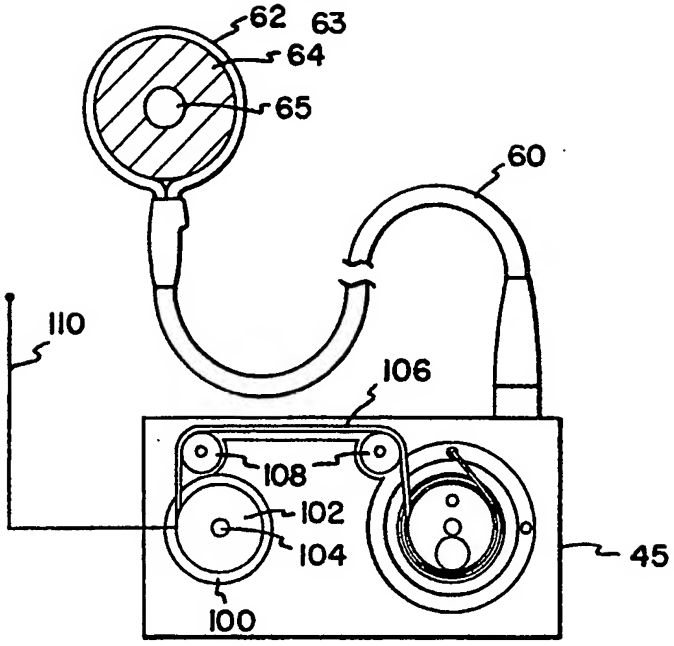


FIG. 4

FIG. 5A

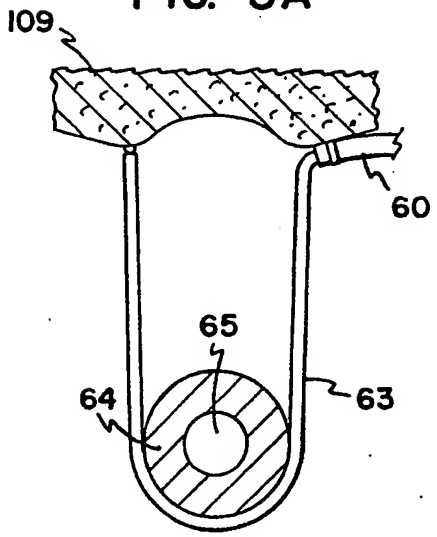


FIG. 5B

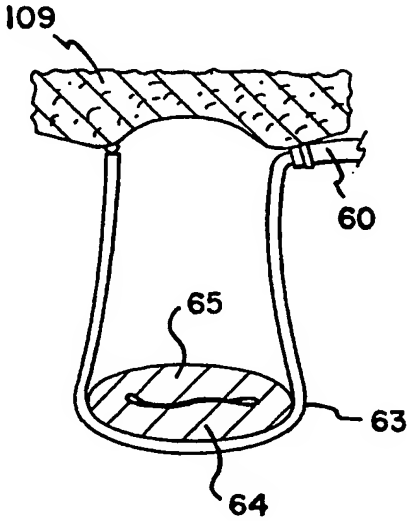


FIG. 6A

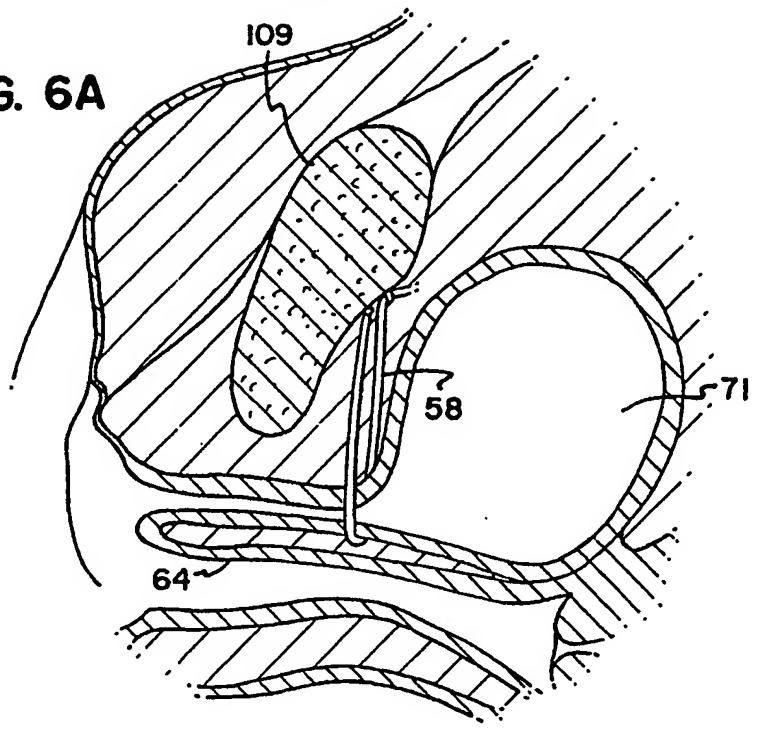
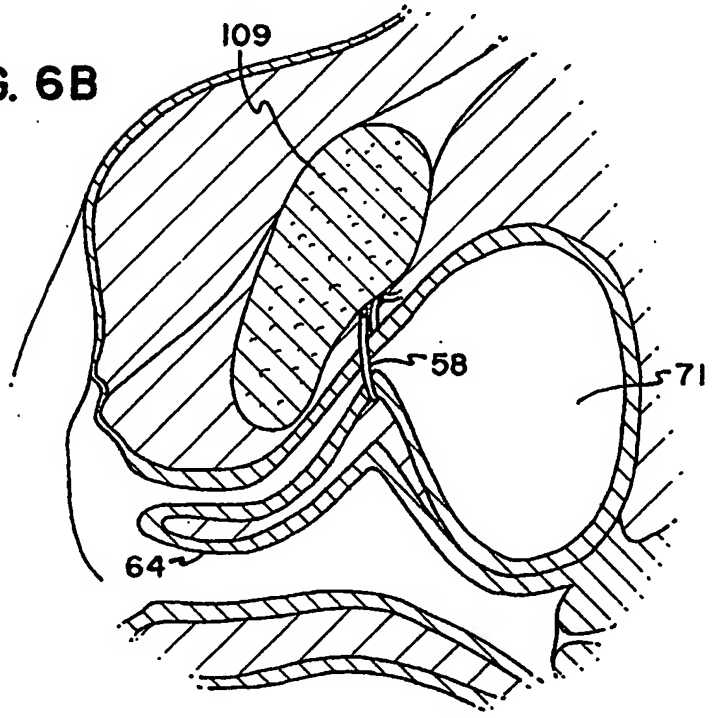


FIG. 6B



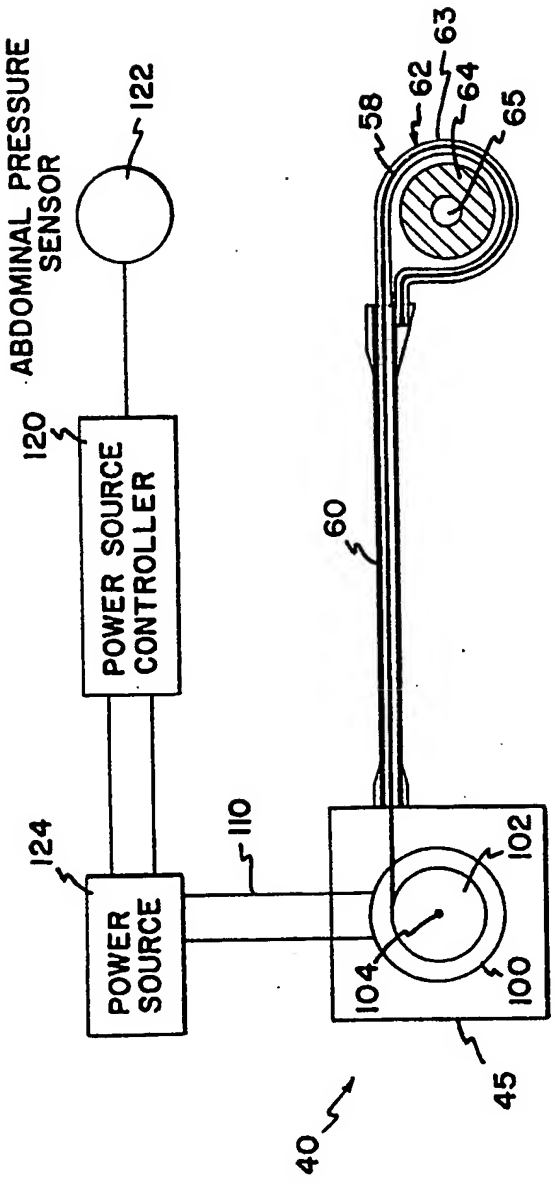

ABDOMINAL PRESSURE SENSOR
122
120
POWER SOURCE CONTROLLER
124
POWER SOURCE
110
58
62
63
64
65
60
102
104
100
45
40

FIG. 7

BH

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 11/00 — A1

(11) International Publication Number: WO 96/34587

(43) International Publication Date: 7 November 1996 (07.11.96)

(21) International Application Number: PCT/US96/05960

(22) International Filing Date: 30 April 1996 (30.04.96)

(30) Priority Data:
08/432,276 1 May 1995 (01.05.95) US

(71) Applicant: UROMED CORPORATION [US/US]; 64 A Street, Needham, MA 02194 (US).

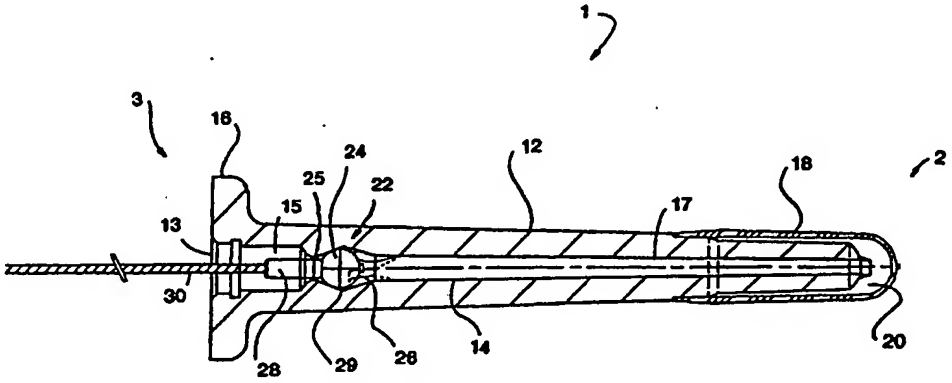
(72) Inventors: SIMON, John, G.; 150 Appleton Street #1C, Boston, MA 02116 (US). WISNOSKY, Carl, J.; 87 E. Charlton, Spencer, MA 01562 (US). McLAUGHLIN, Paul, D.; 30 Wilshire Drive, Scituate, MA 02066 (US). JOSHI, Sharad; 165 Waverley Avenue, Watertown, MA 02172 (US). FELICE, Leo, C.; 75 Eagle Peak Road, Pascoag, RI 02859 (US). COULTER, Christopher, C.; 51 Pettee Street #42, Newton Upper Falls, MA 02164 (US).

(74) Agent: FITZPATRICK, Anne, E.; Lorusso & Loud, 440 Commercial Street, Boston, MA 02109 (US).

(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: FLUIDLY EXPANDABLE URETHRAL PLUG ASSEMBLY WHICH RECEIVES FLUID FROM AN EXTERNAL SOURCE AND METHOD FOR CONTROLLING URINARY INCONTINENCE



(57) Abstract

This invention is a novel urethral plug (1) comprising a cooperating shaft (12) and balloon (18), lying in coaxial engagement. The balloon (18) possesses a contracted shape for insertion and removal through the opening of the urethra, and a larger, expanded shape for blocking the flow of urine in the urethra, bladder neck, and bladder. After insertion such an expanded shape is achieved by inflation of the balloon (18) through the use of an external source such as a syringe which introduces fluid through an opening and into the shaft. The fluid acts upon a ball valve (22), thus pushing the ball past a valve seat, thereby permitting fluid to travel through the shaft and into the balloon (18). Fluid transmission continues until the balloon (18) is expanded to such an extent as to block the flow of urine.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	**GB**	United Kingdom	**MW**	Malawi
AT	Austria	**GE**	Georgia	**MX**	Mexico
AU	Australia	**GN**	Guinea	**NE**	Niger
BB	Barbados	**GR**	Greece	**NL**	Netherlands
BE	Belgium	**HU**	Hungary	**NO**	Norway
BF	Burkina Faso	**IE**	Ireland	**NZ**	New Zealand
BG	Bulgaria	**IT**	Italy	**PL**	Poland
BJ	Benin	**JP**	Japan	**PT**	Portugal
BR	Brazil	**KE**	Kenya	**RO**	Romania
BY	Belarus	**KG**	Kyrgystan	**RU**	Russian Federation
CA	Canada	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CF	Central African Republic			**SE**	Sweden
CG	Congo	**KR**	Republic of Korea	**SG**	Singapore
CH	Switzerland	**KZ**	Kazakhstan	**SI**	Slovenia
CI	Côte d'Ivoire	**LI**	Liechtenstein	**SK**	Slovakia
CM	Cameroon	**LK**	Sri Lanka	**SN**	Senegal
CN	China	**LR**	Liberia	**SZ**	Swaziland
CS	Czechoslovakia	**LT**	Lithuania	**TD**	Chad
CZ	Czech Republic	**LU**	Luxembourg	**TG**	Togo
DE	Germany	**LV**	Latvia	**TJ**	Tajikistan
DK	Denmark	**MC**	Monaco	**TT**	Trinidad and Tobago
EE	Estonia	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**UG**	Uganda
FI	Finland	**ML**	Mali	**US**	United States of America
FR	France	**MN**	Mongolia	**UZ**	Uzbekistan
GA	Gabon	**MR**	Mauritania	**VN**	Viet Nam

FLUIDLY EXPANDABLE URETHRAL PLUG ASSEMBLY WHICH RECEIVES FLUID FROM AN EXTERNAL SOURCE AND METHOD FOR CONTROLLING URINARY INCONTINENCE

Cross Reference To Related Applications

This application is a continuation-in-part of United States application number 08/124,264 filed September 20, 1993 and 08/103,812 filed August 6, 1993. United States application number 08/103,812 is a continuation application of United States application number 07/746,364 filed August 16, 1991 (now abandoned), which is a continuation-in-part application of United States application number 07/636,285 filed December 31, 1990 (now United States Patent No. 5,090,424), the teachings of the foregoing applications and patent being incorporated herein by reference.

DEFINITIONS

Various trademarks appear throughout the specification and claims to describe some of the chemical ingredients comprising the invention. They are identified as follows:

"KRATON G" is a trademark of Shell Oil Company and identifies the product styrene-ethylene/butylene styrene block co-polymer blend.

"C-FLEX" is a trademark of Consolidated Polymer Technologies, Inc. and identifies the product styrene-ethylene/butylene styrene block co-polymer blend.

"SARLINK" is a trademark of DSM Thermoplastic Elastomers Inc. and identifies a dynamically vulcanized thermoplastic elastomer product.

"DACRON" is a trademark of E.I. Du Pont De Nemours and Co. and identifies the product polyethylene terephthalate.

"SANTOPRENE" is a trademark of Monsanto Company and identifies thermoplastic elastomers, and more particularly, styrene block thermoplastic elastomers.

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a novel occlusion device which is inserted into the urethra to control urinary incontinence.

Description of the Prior Art

Urinary stress incontinence is defined as the involuntary loss of urine when the pressure within the urethra exceeds the urethral closure pressure required for maintaining continence. While the problem of urinary incontinence occurs in men and women, it is an affliction especially common in women of child-bearing age and beyond.

There are in existence several methods used to address the problem of incontinence. Bladder neck suspension surgery, wherein the neck of the bladder is reduced by suspending the bladder, is a common way for surgeons to treat incontinence. However, there are numerous risks associated with such surgery, notwithstanding the expense. For some patients, bladder neck

suspension surgery is not recommended for medical or other reasons. For example, in women who previously have undergone bladder neck surgery with unsuccessful results, an additional surgical procedure may be neither appropriate not beneficial. Also, for those with mild incontinence surgery is not always a necessary solution.

Also in existence are a variety of devices for controlling urinary incontinence. Many of these devices require surgery for implantation, and of these surgically implanted devices, there are two distinct types: non-manipulable devices and manipulable devices. One such non-manipulable device, described in United States Patent No. 4,019,499, is a capsule filled with a variable amount of fluid. The capsule is surgically implanted between supporting tissue and the urethra to exert an occluding force thereon. A similar, non-manipulable capsule implant is described in United States Patent No. 3,789,828. However, this device has ties extending therefrom to aid in fiber ingrowth, thus providing mechanical stability to the capsule. One problem associated with this device is the risk of fluid leakage. In addition to problems with leakage, severe tissue damage may result from the unnatural method in which such devices regulate incontinence.

Other surgically implanted devices exist which are manipulable. These devices provide the wearer with the ability to selectively control the operation of the device via manually operable elements implanted in the tissue surrounding the

urethra. United States Patent No. 4,428,365, and United States Patent No. 4,846,784 each disclose an indwelling device having an inflatable chamber with an attached tubing and an inflation bulb. The wearer may manually adjust the pressure exhibited by the inflatable member on the urethra, simply by squeezing the tissue encasing the bulb. These devices, however, often produce thickening and scarring of surrounding tissue, making their usefulness questionable. Additional adverse effects associated with surgically implanted indwelling devices, whether non-manipulable or manipulable in nature, are encrustation, irritation, infection, toxic reactions to materials, tissue necrosis and, occasionally, surgery to remove the device due to device failure or complications.

There are also known in the art, certain indwelling devices that do not require surgical implantation. These devices are inserted by a physician through the urethral orifice and allow the wearer to void either past or through the device. An example of such a device is disclosed in United States Patent No. 4,850,963 in which a physician inserts a bolus of ferromagnetic material through the urethra and into the bladder. The bolus rests at the juncture of the bladder and urethra and is moved for bladder evacuation, by the relative positioning of a magnet across the body of the wearer. However, the bolus may become lodged in an area beyond the reaches of the magnetic force exhibited by the magnet, making the device inoperative. Another example of this type of indwelling device is the prestressed capsule disclosed in United States Patent No. 4,457,299. The capsule is inserted

by a physician within the lower interior of the urethra and is set at a prestressed pressure slightly above involuntary pressure. When the urine pressure exceeds the preset pressure of the capsule, the capsule deforms allowing urine to flow around the device. This device, however, has no feature to prevent migration of the device into the bladder. In United States Patent No. 4,553,533 there is shown a prosthetic urethral sphincter valve which is placed in the urethra and anchored in the bladder. The patient increases his bladder pressure by means of a valsalva maneuver, and holds this pressure while the valve activates. Urine may then pass through the valve with the valve later returning to its closed position. This device is very complicated, expensive, difficult to manufacture and uncomfortable. Another physician-inserted device is disclosed in United States Patent No. 3,797,478. This device has an expandable collar which is inflated after insertion, by an injection of fluid therein. When it is desired to remove the device, the inflated collar must be ruptured or serrated, thus expelling the fluid into the wearer's body. This makes it dangerous and difficult for the wearer to remove. Notwithstanding the cumbrous use of this device, there is a risk of infection associated with the long term indwelling time and with the release of injection fluid upon removal. Similarly, United States Patent No. 3,841,304 discloses a plug which is inserted by a physician into the urethra and subsequently inflated to block the flow of urine. This device may be left in the body for extended periods. After insertion, the device merely requires repositioning in the urethra to permit bladder

evacuation. Such a device leaves the wearer susceptible to infection, as bacteria may be introduced into the urethra during repositioning, or during indwelling time. Also, serious complications can occur upon removal, when a separate wire must be inserted therein. U.S. Patent No. 5,114,398 discloses a flow-through plug which is left in the urethra for as long as desired. The device comprises a shaft having an inflatable balloon prior to its end. The shaft continues through the balloon, the shaft having a proximal opening and cooperating channel through which urine can pass. The excessive length of the shaft can cause irritation and complications such as catheter tip cystitis. The channel is closed by a valve until voiding is desired, at which point the wearer activates the valve causing it to open. Urine that has collected in the bladder then flows through the shaft, and out of the body. It is thus clear that the above devices, being indwelling, are often cumbersome to the wearer and often cause numerous complications such as encrustation, irritation and infection.

Also known in the art are devices capable of being inserted by the wearer into the urethra. Such devices are removed for voiding, and then reintroduced into the urethra upon completion of bladder evacuation. An example of such a device is the solid-type urethral plug, described by Nielsen, Kurt K. et al., in "The Urethral Plug: A New Treatment Modality for Genuine Urinary Stress Incontinence in Women" J. Urology, vol. 44, p. 1100 (1990). This device consists of one or two solid spheres located along a soft shaft, and a thin, soft plate located at the end of

the shaft. One sphere is located upstream of the maximum urethral closing pressure point, corresponding to the location of the sphincter. In the two sphere embodiment, the second sphere is located with its midpoint at the bladder neck, and is used to assist in reducing urinary flow and pressure transmission to the urethra so that the sphincter can operate. When the patient wants to evacuate the bladder, the plug is removed, evacuation occurs, and a fresh plug is inserted. One problem associated with this device is that the patient must have three urethral closure pressure profiles performed as well as other examinations, before the device is made for the wearer. Additional problems associated with this device include placement difficulties, lack of sealing capabilities associated therewith, inadequate retention thereby allowing expelling and inadequate anchoring by the plate at the meatus. In addition to such problems is the discomfort associated with insertion due to the size profile and rigidity of the spheres, which maintain a constant diameter during insertion and removal. Another "remove-to-void" device is disclosed in United States Patent No. 5,090,424, which comprises a conformable urethral plug. The body of the plug forms a cavity which is in fluid communication with another cavity via a check-valve. In that device the fluid used to inflate the plug is integral with the plug.

In view of the above discussion concerning problems and complications associated with prior art devices, it would be desirable to provide an easily manipulable, remove-to-void urethral plug having a fluidly expandable balloon inflated by a

removably coupled external fluid source. Such a device would minimize the discomfort to the wearer while preventing unwanted involuntary flow of urine.

SUMMARY OF THE INVENTION

An object of the invention is to provide a device which controls the unwanted leakage of urine from the urethra.

Another object of the invention is to provide a removable device which arrests involuntary voiding of urine after insertion into the urethra, bladder neck or bladder followed by inflation.

Another object of the invention is to provide a removable urethral plug for preventing unwanted flow of urine which only allows voiding after deflation and removal of the plug by the wearer.

An additional object of the invention is to provide a urethral plug which is easily manipulated by the wearer.

A further object of the invention is to provide a urethral plug made of a material sufficiently stiff for ease of insertion yet sufficiently soft to conform to the urethra during typical body movements.

Another object of the invention is to stabilize the placement of a urethral plug at the urethral meatus, such that migration into the bladder will not occur.

Another object of the invention is to provide a urethral plug capable of anchoring in the urethra, bladder neck or bladder, such that expulsion of the plug from the body will not likely occur.

A further object of the invention is to improve the degree of comfort associated with insertion and removal of a urethral plug.

Yet another object of the invention is to provide a urethral plug assembly comprising an applicator for ease of insertion.

Another object of the invention is to provide a method for controlling incontinence.

Still another object of the invention is to provide a method of using a urethral plug while minimizing risk of contamination.

These and other objects of the invention are carried out by a novel urethral plug sufficiently rigid for ease of insertion into the urethra, yet sufficiently pliable to conform to the size and shape of the urethra during typical body movements. This is achieved by the structural design and material composition of the urethral plug.

The urethral plug comprises a cooperating shaft and balloon, lying in coaxial engagement. The balloon possesses a contracted shape for insertion and removal through the opening of the urethra, and a larger, expanded shape for blocking the flow of urine in the urethra, bladder neck and bladder. The expanded shape also serves to maintain the plug shaft's position in the urethra. Such an expanded shape is achieved by fluid inflation from an external source such as a specially adapted syringe or inflator. A fluid is introduced through an aperture and into a continuous channel in the shaft, whereby it acts upon a ball valve. The force of the fluid pushes the ball past a cooperating

valve seat, thus permitting fluid to travel into the balloon causing it to expand. Once expanded and the external inflation source removed, the balloon retains the fluid therein, as the downward force of the fluid on the ball valve causes the ball to rest firmly against the valve seat. The unique design of the valve chamber in the shaft provides springs which mechanically help re-seat the ball valve when the external inflation source is removed.

Upon expansion, the balloon thus functions to seal the plug to the urethral, bladder neck and bladder wall. The plug further has a meatal plate for preventing migration into the bladder. Deflation of the plug for bladder evacuation, is easily accomplished by pulling a cord attached to the ball towards the proximal end of the plug causing the removal of the ball from the valve seat, thus allowing the fluid contained within the balloon to be expelled. Removal is then easily and comfortably accomplished by grasping a tab attached to the meatal plate, at which point the wearer can void.

In accordance with a further feature of the invention, there is provided an applicator specially adapted to be firmly and removably connected with the urethral plug to assist the wearer in easily locating the urethral opening and inserting the plug into the urethra. After insertion and inflation of the urethral plug, the applicator is easily detached therefrom. An applicator so adapted is advantageous in that it minimizes the risk of infection by eliminating human contact during preparation and

insertion of the urethral plug into the body. For those requiring additional assistance in locating the urethral opening, a specially designed mirror is provided which adapts to the applicator.

In accordance with yet another feature of the invention, there is provided a method for controlling urinary incontinence in humans.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows the preferred embodiment of the urethral plug in its contracted configuration.

FIG. 2 shows the preferred embodiment of the urethral plug in its inflated configuration.

FIG. 3 shows the preferred embodiment of the urethral plug with the valve in an open position permitting deflation.

FIG. 4 shows a perspective view of the meatal plate of the urethral plug of the preferred embodiment.

FIG. 5 shows an applicator for use with the urethral plug of the invention.

FIG. 6 shows a urethral plug assembly in a pre-insertion state.

FIG. 7 shows how a user would open the sterile package of a urethral plug without touching the plug.

FIG. 8 shows an exploded view of an applicator with mirror for use with the urethral plug of the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 shows the plug 1 of the instant invention in its pre-insertion state. The plug 1 of the present invention comprises a shaft portion 12 formed of a biocompatible deformable material. Suitable materials comprising the shaft portion 12 include but are not limited to thermoplastic elastomers and similar materials thereto, in particular, KRATON G, C-FLEX, polyurethane (or other similar thermoplastic urethanes), SARLINK, SANTOPRENE, poly-vinyl chloride, silicone, latex or other rubbers. For ease of insertion, the shaft portion 12 has a tapered tip on its distal end and a maximum diameter of less than 5 mm (15 French).

The shaft portion 12 has a central opening 13 and defines a central channel 14 through which fluid can flow, as is further explained. At the proximal end 3 of the shaft portion 12 is a meatal plate 16 further described in FIG. 4. Attached at the distal end 2 of the shaft portion 12, either by thermal bonding, laminating or other means, is a sealing membrane, or balloon 18, which in its pre-insertion configuration, is adapted to rest against the shaft portion 12. Suitable biocompatible materials comprising the balloon 18 include but are not limited to thermoplastic elastomers and similar materials thereto, in particular, KRATON G, C-FLEX, polyurethane (or other similar thermoplastic urethanes), SARLINK, SANTOPRENE, poly-vinyl chloride, silicone, latex or other rubbers. Channel 14 is in fluid communication with the interior 20 of the balloon 18. Positioned within the channel 14 is a chamber 29, which comprises

a ball valve 22. The ball valve 22 includes ball 24 and a valve seat 25. The chamber 29 further provides springs 26, which increase the elastomeric tension of the chamber 29.

Suitable biocompatible materials for ball valve 22 include but are not limited to polypropylene, polyestertetraphalate, silk, DACRON, nylon and other similar thermoplastic materials. The most preferred material is nylon. Connected to the ball 24 is ball shaft 28 and cooperating cord 30. Materials suitable for cord 30 include but are not limited to polypropylene, polyester-tetraphalate, silk, DACRON, and other similar thermoplastic materials, with the most preferred material being nylon. In addition, a lubricant which aids in sealing and removing of the plug 1 can be applied internally to the valve seat 25. Suitable materials comprising the lubricant include but are not limited to propylene glycol (PPG), glycol, glycerin and silicone oil, with the most preferred material being polyethylene glycol (PEG). As to be discussed with respect to FIG. 2, a fluid source is adapted to be coupled with the plug 1 at the central opening 13 to transmit fluid past the ball valve 22 in the direction of the arrow to cause expansion of the balloon 18.

FIG. 2 shows the urethral plug 1 of the instant invention in its inflated and blocking state. To achieve this state, the wearer inserts the plug 1 into the urethra while it is in its pre-insertion configuration as shown in FIG. 1. The force required to insert the plug 1 is preferably less than 0.2 kg and, more preferably, less than 0.1 kg. Once inserted, fluid is then

introduced into the channel 14 of shaft portion 12 by means of a conduit coupling 32 positioned at the central opening 13. The conduit coupling 32 can be the nozzle of a syringe, an inflator, a hose, or the like. In order for the fluid to enter the channel 14 of the shaft portion 12, the fluid must pass through a wide portion 15 of the channel 14 and displace the ball 24. When pressure is exerted through the wide portion 15 of the channel 14 in the direction shown by the arrows, the force of the fluid causes the ball 24 to move towards the distal end 2 of the plug 1. As the ball 24 moves toward distal end 2, it pushes against and temporarily deforms springs 26. Fluid is thereby allowed to pass into the narrower portion 17 of the channel 14 and ultimately into the balloon 18. The pressure required to inflate the plug 1 is preferably in the range of 1-20 psi, and more preferably 1-12 psi. The balloon 18 is inflated to a maximum diameter of less than 2.0 inches, preferably on the order of 0.4 inches to 1.0 inch, thereby sealing the device against the walls of the urethra, bladder neck or bladder to prevent incontinence.

At such time when sufficient fluid has been introduced to inflate the balloon 18, the back pressure of fluid in the balloon 18, together with the force exerted by springs 26, pushes the ball 24 towards the proximal end 3 of the plug 1 such that it again rests on the valve seat 25. The flow of fluid back through the ball valve 22 through which it entered is thereby prevented. At this point, the internal pressure within the balloon may reach a maximum of 15 psi, with a preferable range of about 6-13 psi. The balloon 18 in its inflated state serves to resist internal

bladder pressure spikes of up to 3.0 psi (210 cm H_2O). Such bladder pressures would tend to expel the plug 1 unwarrantedly, for example, during coughing unless the balloon has been inflated.

As shown in FIG. 3, when the wearer wishes to void, voiding is accomplished by grasping cord 30 and pulling it in a direction away from the proximal end 3 of the plug 1. This will exhibit a force on the ball 24 causing deformation of valve seat 25, thus allowing the ball 24 to move towards the proximal end 3 of the plug 1 and into the widened portion 15 of channel 14. The amount of force to be applied to the cord 30, and pull the ball 24 into the widened portion 15, is less than 1.5 lb., and preferably less than 0.8 lb for optimum comfort. Alternatively, the valve seat 25 can be deformed directly by pinching the plug 1 just above the meatal plate.

Either deflation means will allow fluid from the balloon 18 to be expelled through the channel 14, whereupon it exits the plug 1 through the central opening 13. Once the fluid in the balloon 18 has been expelled, the wearer can grasp the meatal plate 16 for removal of the plug. The force required to remove the plug 1 after deflation is preferably less than 0.1 kg and, more preferably, less than 0.05 kg to assure comfort of the wearer while removing the plug 1. Once removed and bladder evacuation accomplished, the wearer can insert a new plug. The used urethral plug 1 is disposed of through ordinary trash means.

To maintain sterility and minimize the risk of urinary tract

infections, the urethral plug 1 of the invention has been designed to prevent re-use of the plug 1 after removal from the body. In an exemplary embodiment, this is accomplished when the ball 24 is disposed in the widened portion 15 of channel 14. In this way the ball valve 22 becomes inoperable so the urethral plug 1 cannot be re-used, i.e., cannot be re-inflated by the wearer. It should be recognized that it is within the scope of the present invention to use any means known in the art for controlling the flow of fluid into and out of the balloon 18, as well as means for rendering the valve inoperable to prevent re-use of the urethral plug 1.

FIG. 4 shows a perspective view of the meatal plate 16. The meatal plate 16 is adapted to anchor the urethral plug 1 at the meatus urinarius. To carry out this function of anchoring, the meatal plate 16 is of a thickness preferably in the range of about 1.0 mm to about 3.0 mm, with the most preferred thickness being 2.5 mm. This range of thickness of the meatal plate is sufficient to withstand bodily compression during wear. The meatal plate 16 is preferably greater than 8.0 mm in diameter, a diameter generally sufficient to prevent migration into the bladder. A portion of the meatal plate 16 is extended to form a flexible tab 17 which may be grasped by the wearer to remove the plug 1. The meatal tab 17 is of a preferred thickness of about 0.5 mm to about 2.0 mm for comfort and ease of removal.

The meatal plate 16 has an aperture therein which forms the central opening 13 to the shaft portion 12. The meatal plate 16

prevents the plug 1 from passing through the opening of the urethra ultimately leading into the bladder neck or bladder.

As shown in FIGS. 5 and 6, an applicator 40 is separately provided to assist the wearer in easily locating the urethral opening and inserting the urethral plug 1 into the urethra. A further advantage of the applicator 40 is to minimize the risk of infection by eliminating human contact during preparation of the urethral plug assembly 50, as shown in FIG. 6. This is accomplished by the sterile packaging of the plug together with the practice of the following method. The user takes the applicator 40 from its sterile package and fully withdraws the plunger 42 to a position as shown in FIG. 6. FIG. 7 shows the wearer partially opening a package containing a sterile urethral plug 1 so as to expose the meatal plate 16 and chord 30, as shown. The partially opened package 52 containing the exposed plug 1 now serves as a protective sheath, thereby preventing human contact with the sterile plug 1 while attaching the applicator 40. Grasping the partially opened package 52, the user guides the cord 30 into the opening (not shown) in the conduit coupling 32 of the applicator 40 until the tip 49 of conduit coupling 32 forms a snap-fit with the central opening 13 of the meatal plate 16. Holding the urethral plug assembly 50 with one hand, the wearer positions the urethral plug assembly 50 at the urethral opening and inserts the plug 1 into the urethra until the meatal plate 16 contacts the opening. The wearer depresses the plunger 42 until the stop 44 abuts the applicator flange 46 of barrel 47. The balloon 18 of plug 1 is

now fully inflated, as shown in FIG. 3. The applicator 40 is disengaged from the plug 1 by gently tilting in an upward direction.

The conduit coupling tip 49 and the meatal plate central opening 13 are removably connected by any of a number of means known in the art, including but not limited to snap-fit/de-fit type of connections and twisting and locking type of connections, that can establish a fluid pressure boundary, while retaining the ability to be easily removed without significantly disturbing the urethral plug 1 positioned and secured in the urethra. Preferably, the conduit coupling tip 49 and the meatal plate central opening 13 are interconnected by means of a snap-fit/de-fit type of connection, where the coupling/decoupling force is up to about 8 lbs, and preferably is a force of up to 6 lbs, and most preferably, is a force of about 1 lb or less.

As a further aid in easily and accurately locating the urethral opening, a mirror 60 is provided, as shown in FIG. 8, which may be affixed to the barrel 47 of the applicator 40. One embodiment provides for the attachment of the mirror 60 with a clasp 62.

While the invention has been particularly shown and described with reference to the aforementioned embodiments, it will be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention. Thus, any modifica-

tion of the shape, configuration and composition of the elements comprising the invention is within the scope of the present invention. For example, the ball valve 22 described above may be located at various points along channel 14 of the plug 1.

We hereby claim:

1. A remove-to-void plug for use in the urethra to control urinary incontinence, said plug to be inserted into the urethral opening, comprising:

a plug forming body being closed to urine and having a proximal end and a distal end,

a fluid-impermeable balloon affixed to the distal end of said plug forming body and fluidly coupled with said channel, said balloon having an outer surface free of protrusions,

a valve positioned within said channel of said plug forming body,

a fluid source external to said plug forming body, said fluid source being removably coupled to the proximal end of said plug forming body, said fluid source transmitting fluid through said channel, displacing said valve and inflating said balloon, said valve being reversely displaced after inflation to maintain said balloon in an inflated state.

2. The remove-to-void plug according to claim 1, said valve comprising a ball and a ball seat, respectively.

3. The remove-to-void plug according to claim 2, whereby said fluid transmitted by said fluid source displaces said ball from said ball seat.

4. The remove-to-void plug according to claim 2, whereby said valve maintains said balloon in an inflated state by a reverse pressure of said fluid which forces said ball against said ball seat.

5. The remove-to-void plug according to claim 2, said valve further comprising a cord adapted to exert a force on said ball to release said ball from its position against said ball seat whereby said balloon deflates.

6. The remove-to-void plug according to claim 5, whereby the force to be applied to said cord is less than 1.5 lb.

7. The remove-to-void plug according to claim 6, whereby the force to be applied to said cord is less than 0.8 lb.

8. The remove-to-void plug according to claim 2, said valve further comprising a chamber having a plurality of springs protruding in said chamber, said plurality of springs being adapted to retain said ball in said chamber.

9. The remove-to-void plug according to claim 1, said valve comprising a biocompatible material selected from the group consisting of polyestertetraphalate, polypropylene, silk, polyethylene terephthalate, nylon and other similar thermoplastic materials.

10. The remove-to-void plug according to claim 9 wherein the biocompatible material is nylon.

11. The remove-to-void plug according to claim 5 wherein said cord comprises a biocompatible material selected from the group consisting of polyestertetraphalate, polypropylene, silk, polyethylene terephthalate, nylon and other similar thermoplastic materials.

12. The remove-to-void plug according to claim 11 wherein the biocompatible material is nylon.

13. The remove-to-void plug according to claim 1, said valve further including a lubricant, said lubricant selected from the group consisting of propylene glycol, glycol, glycerin, silicone oil and polyethylene glycol.

14. The remove-to-void plug according to claim 13 wherein said lubricant is polyethylene glycol.

15. The remove-to-void plug according to claim 1, wherein said fluid source comprises an applicator adapted to connect to the proximal end of said plug forming body.

16. The remove-to-void plug according to claim 15, wherein said applicator comprises a syringe or inflator.

17. The remove-to-void plug according to claim 1, said plug forming body further comprising a meatal plate adapted to anchor said plug at the urethral meatus.

18. The remove-to-void plug according to claim 17, said meatal plate having a thickness in the range of about 1-3 mm.

19. The remove-to-void plug according to claim 18, said meatal plate having a thickness of 2.5 mm.

20. The remove-to-void plug according to claim 17, said meatal plate comprising a tab extending therefrom, whereby said plug may be easily removed by a wearer when bladder evacuation is desired.

21. The remove-to-void plug according to claim 1, wherein said plug forming body comprises a thermoplastic elastomer.

22. The remove-to-void plug according to claim 1, wherein said plug forming body comprises a biocompatible material selected from the group consisting of polyurethane, silicone, latex, polyvinyl chloride and styrene-ethylene/butylene styrene block copolymer.

23. The remove-to-void plug according to claim 1, wherein said balloon comprises a thermoplastic elastomer.

24. The remove-to-void plug according to claim 1, wherein said balloon comprises a biocompatible material selected from the

group consisting of polyurethane, silicone, latex, poly-vinyl chloride and styrene-ethylene/butylene styrene block co-polymer.

25. The remove-to-void plug according to claim 1, wherein said plug forming body comprises a shaft portion having a tapered tip on the distal end and a maximum diameter of less than 5 mm, said remove-to-void plug having a force of insertion of less than 0.2 kg and a force of expulsion of less than 0.1 kg with said balloon in a deflated state.

26. The remove-to-void plug according to claim 1, said balloon further having an inflation pressure in the range of about 1-20 psi and a diameter of inflation in the range of about 0.4-1 inch.

27. The remove-to-void plug according to claim 1, wherein said external fluid source further comprises a mirror.

28. The remove-to-void plug according to claim 1, wherein said plug forming body and said external fluid source are removably coupled with a snap-fit/de-fit type of connection.

29. The remove-to-void plug according to claim 1, wherein said plug forming body and said external fluid source are removably
coupled so the connection is made and broken by applying a force of about 8 lbs or less.

30. The remove-to-void plug according to claim 29, wherein said plug forming body and said external fluid source are removably
coupled so the connection is made and broken by applying a force of about 1 lb or less.

31. The remove-to-void plug according to claim 1, wherein said valve includes a means for preventing re-use of the plug by the wearer.

32. A remove-to-void plug for use in the urethra to control urinary incontinence, said plug to be inserted into the urethral opening, comprising:

a plug forming body closed to urine and having a distal end and a proximal end, said plug forming body defining a channel therein,

a fluid-impermeable balloon affixed to the distal end of said plug forming body and fluidly coupled with said channel, said balloon having an outer surface free of protrusions,

a valve positioned within said channel of said plug forming body, said valve comprising a ball and a ball seat, respectively, said ball further comprising a cord affixed thereto,

a fluid source external to said plug forming body, said fluid source being removably coupled to the proximal end of said plug forming body, said fluid source transmitting fluid through said channel, displacing said ball from said ball seat and inflating said balloon, said ball reversely displaced against said ball seat after inflation to maintain said balloon in an

inflated state, and

wherein a force applied to said cord releases said ball from its position against said ball seat causing deflation of said balloon.

33. The remove-to-void plug according to claim 32, said valve further comprising a chamber having a plurality of springs protruding in said chamber, said plurality of springs being adapted to retain said ball in said chamber.

34. The remove-to-void plug according to claim 32, wherein said fluid source comprises a syringe adapted to connect to the proximal end of said plug forming body.

35. The remove-to-void plug according to claim 32, said plug forming body further comprising a meatal plate adapted to anchor said plug at the urethral meatus.

36. The remove-to-void plug according to claim 31, said meatal plate having a thickness in the range of about 1-3 mm.

37. The remove-to-void plug according to claim 36, said meatal plate having a thickness of 2.5 mm.

38. The remove-to-void plug according to claim 35, said meatal plate comprising a tab extending therefrom, whereby said plug may be easily removed by a wearer when bladder evacuation is desired.

39. A urethral plug assembly for prevention of urinary incontinence comprising:

a plug forming body and having a distal end and a proximal end, said plug forming body defining a single channel therein,

a fluid-impermeable balloon affixed to the distal end of said plug forming body and fluidly coupled with said channel, said balloon having an outer surface free of protrusions,

a valve positioned within said channel of said plug forming body,

an applicator for positioning said plug in the urethra of a wearer, said applicator comprising

a barrel having a coupling conduit for retaining said plug, and

a plunger disposed in said barrel, said plunger adapted to push a fluid through said barrel and into said channel, said applicator being removably coupled to the proximal end of said plug forming body, said applicator transmitting said fluid through said channel and displacing said valve to inflate said balloon, said valve being reversely displaced after inflation to maintain said balloon in an inflated state.

40. The urethral plug assembly according to claim 39, said plug forming body further comprising a meatal plate adapted to anchor said plug at the urethral meatus.

41. The remove-to-void plug according to claim 40, said meatal plate having a thickness in the range of about 1-3 mm.

42. The remove-to-void plug according to claim 42, said meatal plate having a thickness of 2.5 mm.

43. The urethral plug assembly according to claim 40, said meatal plate comprising a tab extending therefrom, whereby said plug may be easily removed by a wearer when bladder evacuation is desired.

44. The urethral plug assembly according to claim 39, wherein said applicator further comprises a mirror.

45. A method for controlling urinary incontinence comprising the following steps:

a) providing a urethral plug being closed to urine comprising; a plug forming body having a balloon affixed to the periphery thereof, said balloon being in fluid communication with said channel,

b) inserting said urethral plug into the urethra via the urethral opening,

c) transmitting fluid from an external fluid source through said inner channel causing inflation of said balloon,

d) blocking the flow of urine with said balloon in its inflated state,

e) pulling on a member integral with said urethral plug to deflate said balloon when the wearer wishes to void,

f) removing said plug to void,

g) repeating steps a)-f) with a new plug.

46. The method for controlling urinary incontinence according to claim 45 wherein said providing step further includes providing a mirror.

47. A method for controlling urinary incontinence comprising the following steps:

a) providing a urethral plug comprising; a plug forming body having a channel therein, an opening in the proximal end of said plug forming body, a balloon affixed to a distal end of said plug forming body, said channel fluidly connecting said opening with said balloon, and a valve positioned within said channel having an integral removal member connected thereto,

b) placing an external fluid source in fluid communication with said opening,

c) inserting said urethral plug into the urethra via the urethral opening,

d) transmitting fluid from said fluid source through said channel causing displacement of said valve to allow fluid to pass therethrough,

e) fluidly inflating said balloon,

f) withdrawing said external fluid source from communication with said opening,

g) blocking the flow of urine with said plug until voiding of the bladder is desired,

h) pulling on said integral removal member causing said valve to open and said balloon to deflate,

i) removing said plug,

j) voiding the bladder,

k) repeating steps a)-j) with a new plug.

48. The method for controlling urinary incontinence according to claim 47, wherein said providing step further includes providing a mirror removably affixed to said external fluid source.

49. The method for controlling urinary incontinence according to claim 47, wherein said steps of placing and withdrawing further includes a force of about 8 lbs or less to place and withdraw said external fluid source.

50. The method for controlling urinary incontinence according to claim 49, wherein said steps of placing and withdrawing further includes a force of about 1 lb or less to place and withdraw said external fluid source.

51. A method for controlling urinary incontinence comprising the following steps:

a) providing a urethral plug assembly comprising;

a plug forming body having an opening in the proximal end of said plug forming body, a balloon affixed to the distal end of said plug forming body, said channel fluidly connecting said opening with said balloon, said balloon being in fluid communication with said channel,

an applicator for retaining said plug without human contact, said applicator adapted to push a fluid into said channel, said applicator being removably coupled to the proximal

end of said plug forming body, and

a mirror for attaching to said applicator;

b) attaching said mirror to said applicator;

c) positioning said urethral plug assembly at the urethral opening,

d) inserting said urethral plug into the urethra via the urethral opening,

e) manipulating the applicator whereby said fluid is transmitted from said applicator into said channel of said plug, causing inflation of said balloon,

f) removing said applicator from said opening in the proximal end of said plug forming body,

g) blocking the flow of urine with said balloon in its inflated state,

h) pulling on a member integral with said urethral plug to deflate said balloon when the wearer wishes to void,

i) removing said plug to void.

52. The method according to claim 51, further comprising the step of repeating steps a)-i) with a new plug.

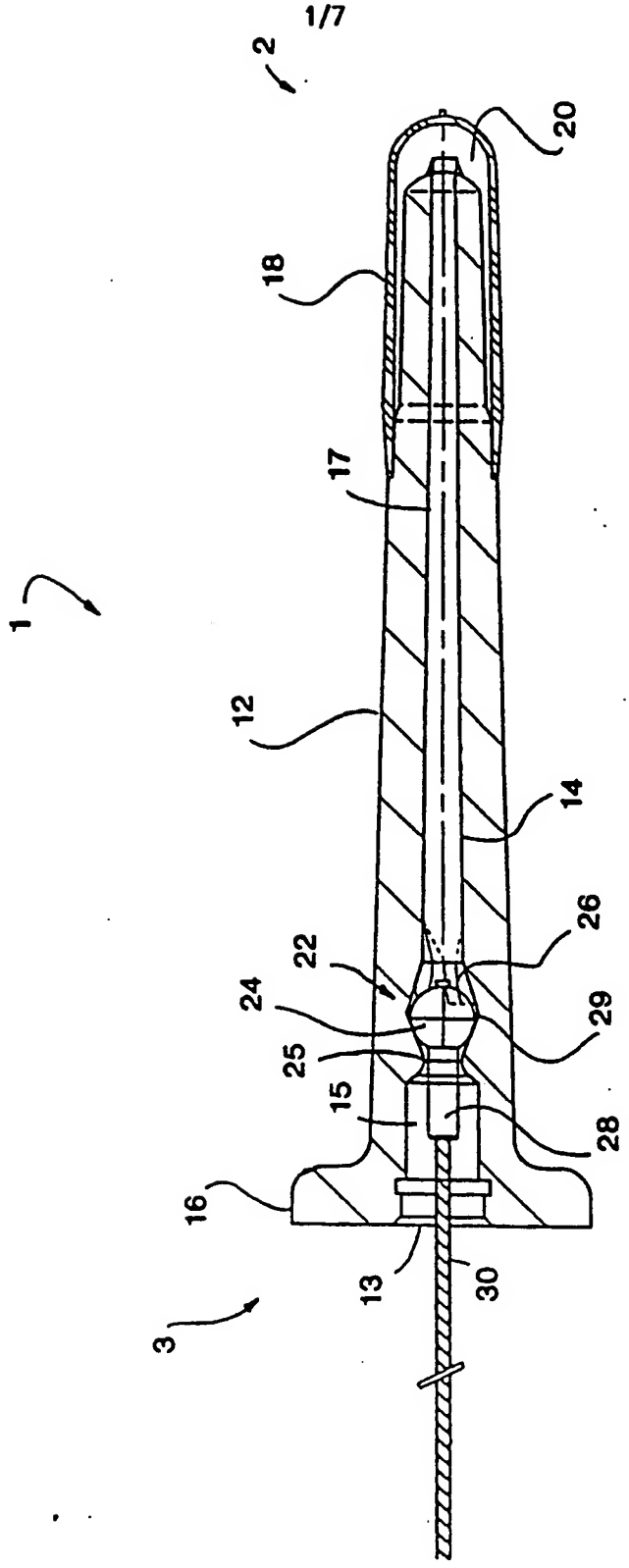


FIG. 1

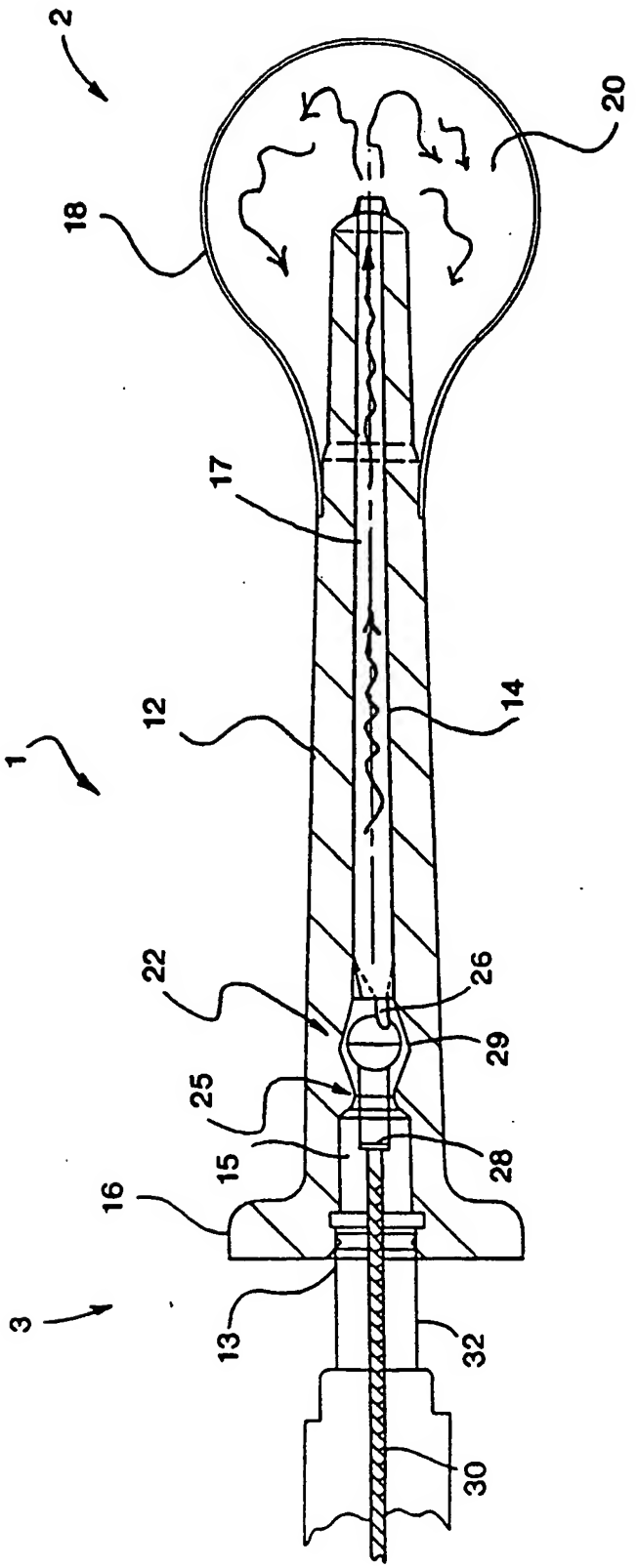


FIG. 2

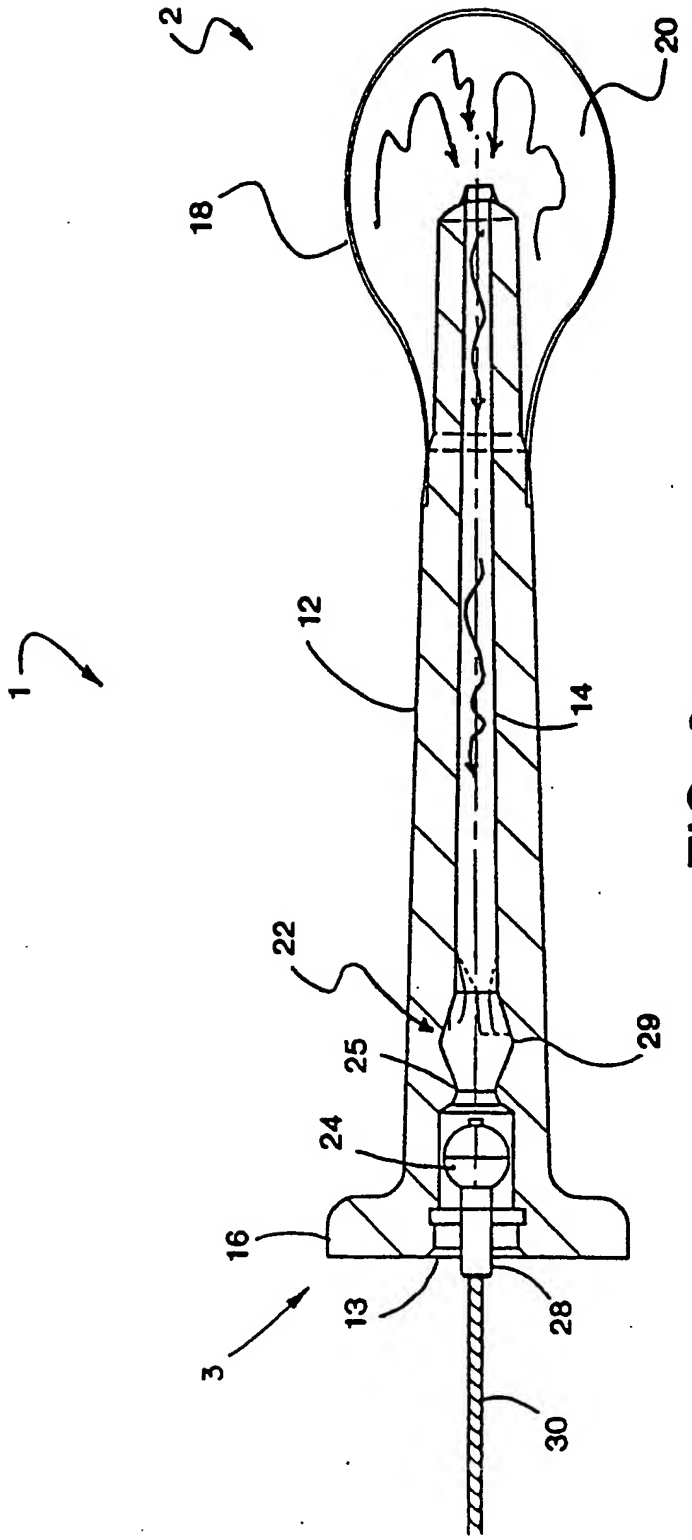


FIG. 3

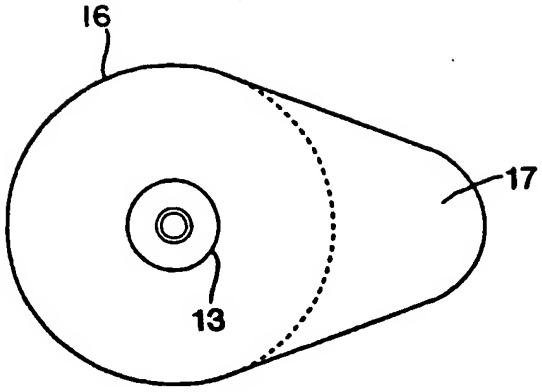


FIG. 4

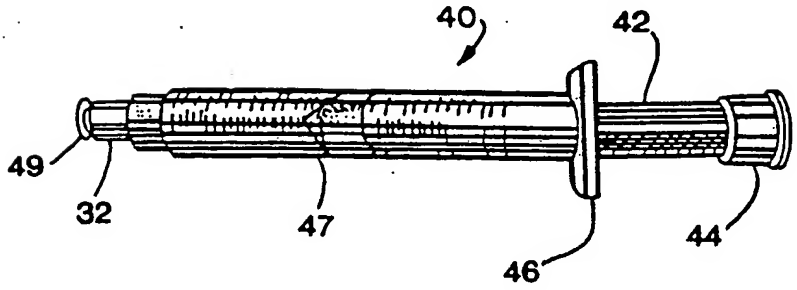


FIG. 5

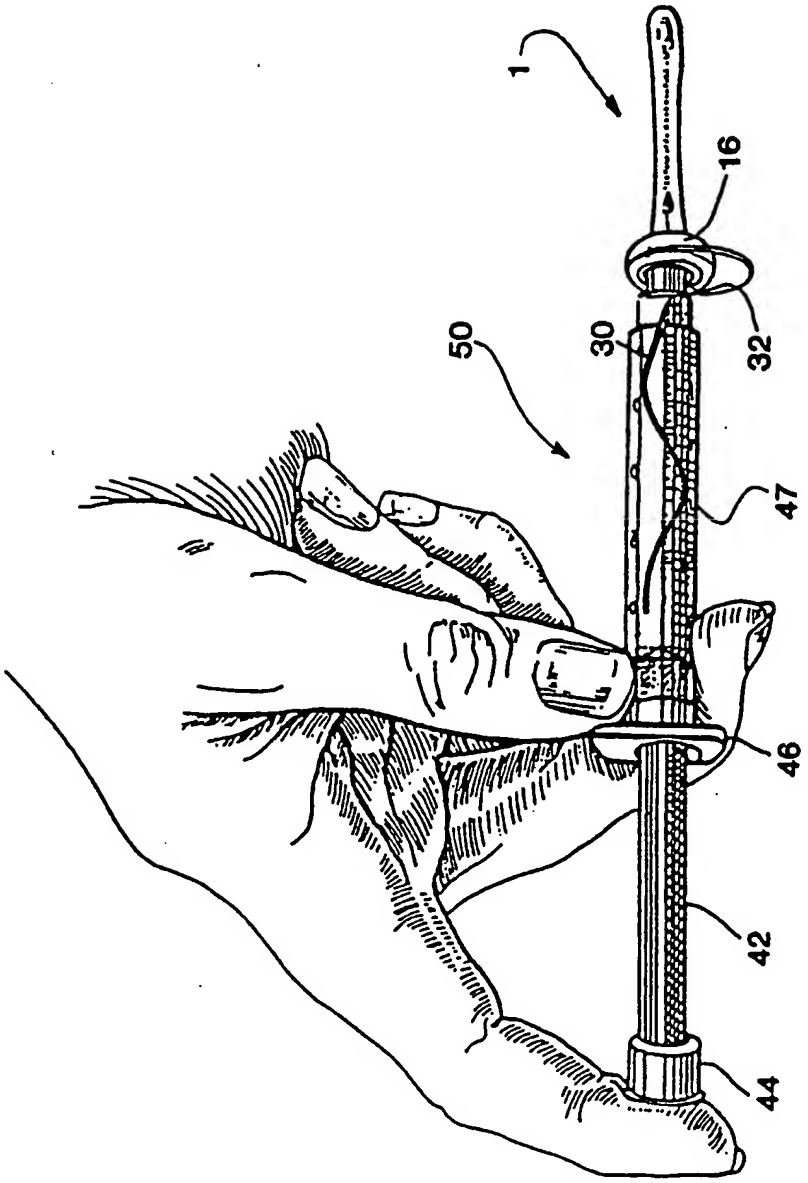


FIG. 6

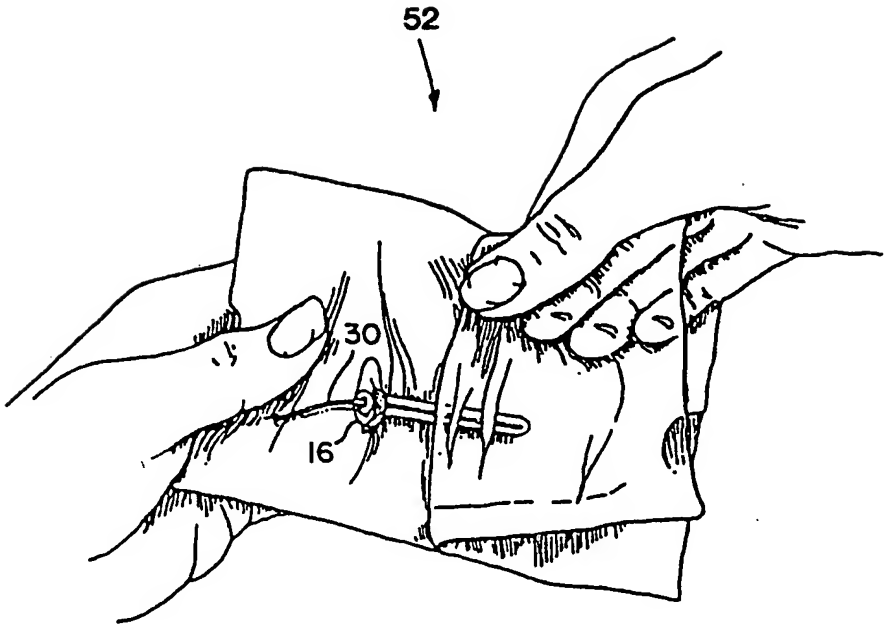


FIG. 7

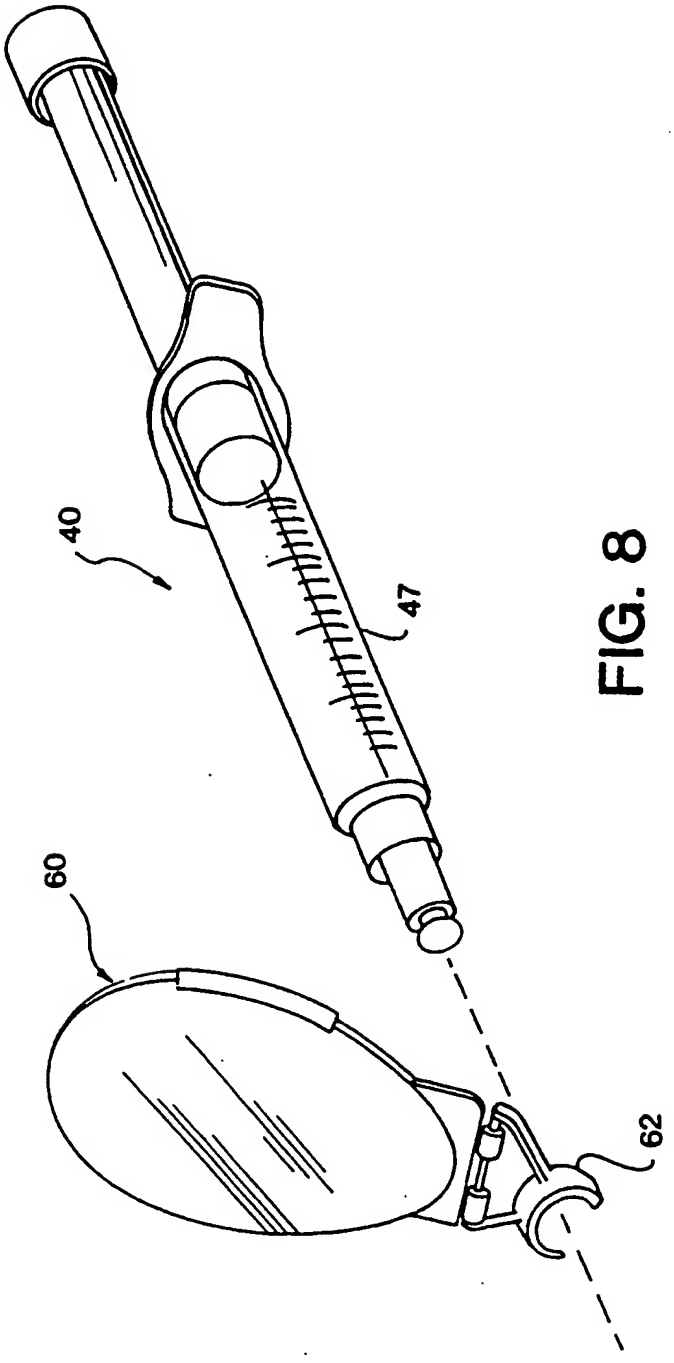


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/05960

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 11/00
US CL :128/885
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/846, 885, DIG. 23; 600/29-31

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 2,494,393 (O. F. LAMSON) 10 January 1950, see the entire document.	1-4, 15, 16, 21, 23, 24, 28, 45 --- 11, 25, 26, 29, 30
A	US, A, 3,841,304 (JONES) 15 October 1974, see the entire document.	1-52
A	US, A, 2,638,093 (G. KULICK) 12 May 1953, see the entire document.	1-52
A	US, A, 3,646,929 (BONNAR) 07 March 1972, see the entire document.	1-52

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 JUNE 1996	29 JUL 1996

Name and mailing address of the ISA/US	Authorized officer
Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	MICHAEL A. BROWN
Facsimile No. (703) 305-3230	Telephone No. (703) 308-2682

Form PCT/ISA/210 (second sheet)(July 1992)*

B1

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61N 5/02 | A1

(11) International Publication Number: WO 96/39227

(43) International Publication Date: 12 December 1996 (12.12.96)

(21) International Application Number: PCT/US96/07878

(22) International Filing Date: 29 May 1996 (29.05.96)

(30) Priority Data:
08/469,201 6 June 1995 (06.06.95) US

(71) Applicant: UROLOGIX, INC. [US/US]; 14405 21st Avenue North, Minneapolis, MN 55427 (US).

(72) Inventors: THOME, Scott, P.; 535 Aberdeen Drive, Waite Park, MN 56387 (US). FLACHMAN, Jonathan, L.; 3300 Kyle Avenue North, Minneapolis, MN 55422 (US).

(74) Agent: GRUNZWEIG, Paul, S.; Kinney & Lange, P.A., Suite 1500, 625 Fourth Avenue South, Minneapolis, MN 55415-1659 (US).

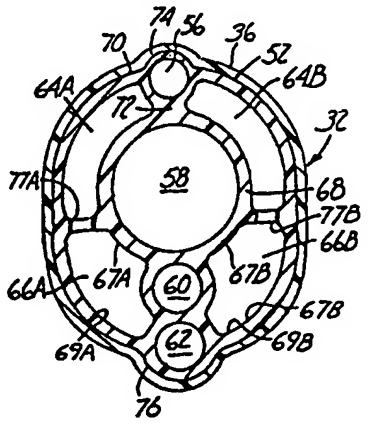
(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: DEVICE FOR TRANSURETHRAL THERMAL THERAPY

(57) Abstract

An intraurethral catheter shaft (32) comprises a plurality of lumens extending between a first end and a second end of the shaft (32). An antenna lumen (58) has a generally circular cross-sectional surface area and is positioned nearer a first outer surface (70) than a second outer surface (76) of the catheter shaft (32). A first and second pair of cooling lumens (64A, 64B and 66A, 66B) substantially surround the antenna lumen (58) and have a generally arc shaped cross-sectional surface area. The cooling lumens are configured to be circumjacent to the antenna lumen (58) about a substantial majority of the antenna lumen (58). A urinary drainage lumen (60) is positioned between the second pair of cooling lumens (66A, 66B) adjacent the antenna lumen (58) and has a generally circular cross-sectional surface area. The lumens of the catheter shaft (32) are defined by a unitary wall (68) having a substantially uniform thickness throughout the catheter (28).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgystan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SG	Singapore
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LR	Liberia	SZ	Swaziland
CS	Czechoslovakia	LT	Lithuania	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	LV	Latvia	TJ	Tajikistan
DK	Denmark	MC	Monaco	TT	Trinidad and Tobago
EE	Estonia	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	UG	Uganda
FI	Finland	ML	Mali	US	United States of America
FR	France	MN	Mongolia	UZ	Uzbekistan
GA	Gabon	MR	Mauritania	VN	Viet Nam

DEVICE FOR TRANSURETHRAL THERMAL THERAPY

BACKGROUND OF THE INVENTION

The present invention relates to the field of microwave thermal therapy of tissue. In particular, the present invention relates to a catheter for transurethral microwave thermal therapy of benign prostatic hyperplasia (BPH).

The prostate gland is a complex, chestnut-shaped organ which encircles the urethra immediately below the bladder. Nearly one third of the prostate tissue anterior to the urethra consists of fibromuscular tissue that is anatomically and functionally related to the urethra and bladder. The remaining two thirds of the prostate is generally posterior to the urethra and is comprised of glandular tissue.

This relatively small organ, which is the most frequently diseased of all internal organs, is the site of a common affliction among older men: BPH (benign prostatic hyperplasia). BPH is a nonmalignant, bilateral nodular expansion of prostrate tissue in the transition zone, a periurethral region of the prostate between the fibromuscular tissue and the glandular tissue. The degree of nodular expansion within the transition zone tends to be greatest anterior and lateral to the urethra, relative to the posterior-most region of the urethra. Left untreated, BPH causes obstruction of the urethra which usually results in increased urinary frequency, urgency, incontinence, nocturia and slow or interrupted urinary stream. BPH may also result in more severe complications, such as urinary tract infection, acute urinary retention, hydronephrosis and uraemia.

Traditionally, the most frequent treatment for BPH has been surgery (transurethral resection). Surgery, however, is often not an available method of treatment for a variety of reasons. First, due to the advanced age of many patients with BPH, other health problems, such as cardiovascular disease, can warrant against surgical intervention. Second, potential complications associated with transurethral surgery, such as hemorrhage, anesthetic

complications, urinary infection, dysuria, incontinence and retrograde ejaculation, can adversely affect a patient's willingness to undergo such a procedure.

A fairly recent alternative treatment method for BPH involves microwave thermal therapy, in which microwave energy is employed to elevate the temperature of tissue surrounding the prostatic urethra above about 45°C, thereby thermally damaging the tumorous tissue. Delivery of microwave energy to tumorous prostatic tissue is generally accomplished by a microwave antenna-containing applicator, which is positioned within a body cavity adjacent the prostate gland. The microwave antenna, when energized, heats adjacent tissue due to molecular excitation and generates a cylindrically symmetrical radiation pattern which encompasses and necroses the tumorous prostatic tissue. The necrosed intraprostatic tissue is subsequently reabsorbed by the body, thereby relieving an individual from the symptoms of BPH.

One method of microwave thermal therapy described in the art includes intrarectal insertion of a microwave antenna-containing applicator. Heat generated by the antenna's electromagnetic field is monitored by a sensor which is positioned near the prostate gland by a urethral catheter. Because of the distance between the rectum and the tumorous prostatic tissue of the transition zone, however, healthy intervening tissue within the cylindrically symmetrical radiation pattern is also damaged in the course of intrarectal treatment. Intrarectal microwave thermal therapy applicators are described in the following references: Eshel et al. U.S. Patent No. 4,813,429; and A. Yerushalmi et al. Localized Deep Microwave Hyperthermia in the Treatment of Poor Operative Risk Patients with Benign Prostatic Hyperplasia, 133 JOURNAL OF UROLOGY 873 (1985).

A safer and more effective treatment of BPH is transurethral microwave thermal therapy. This method of treatment minimizes the distance between a microwave antenna-containing applicator and the transition zone of

the prostate by positioning a Foley-type catheter-bearing applicator adjacent to the prostate gland within the urethra. Due to the close proximity of the microwave antenna to the prostate, a lesser volume of tissue is exposed to the cylindrically symmetrical radiation pattern generated by the microwave antenna, thereby minimizing the amount of healthy tissue necrosed. Intraurethral applicators of the type described can be found in Turner et al. U.S. Patent 4,967,765 and Hascoet et al. European Patent Application 89403199.6.

Recent improvements in transurethral thermal therapy catheter design have resulted in even more effective application of microwave radiation applied to prostatic tissue. For instance, recent transurethral catheters such as that described in Rudie U.S. Patent No. 5,413,588, issued May 9, 1995, include shafts having a multiplicity of lumens arranged about a lumen carrying a microwave antenna. The antenna lumen is oriented nearer a first side of the catheter shaft than a second side of the catheter shaft to position the microwave radiation closer to the first side of the catheter. Cooling lumens are arranged about the microwave antenna lumen to absorb a portion of the microwave radiation so that a greater amount of microwave radiation is absorbed on a second side of the catheter shaft than the first side. This arrangement creates an asymmetrical microwave radiation pattern to permit focusing a greater amount of microwave radiation toward a selected tissue, such as prostatic tissue anterior and lateral to the urethra. This transurethral catheter design also includes a lumen to facilitate urinary drainage from the bladder through the urethra during a treatment session.

SUMMARY OF THE INVENTION

The present invention is based upon the recognition that although the catheter disclosed in Rudie et al. U.S. Patent No. 5,413,588 offers a substantial improvement over previous designs, transurethral catheter designs can still be improved. In particular, improvements can still be made in maintaining consistent urine drainage, increasing antenna tuning consistency,

maximizing selective energy absorption of the area immediately surrounding the microwave antenna lumen, and simplifying manufacture of the catheter shaft while improving its structural integrity. In addition, transurethral catheter designs can be improved to facilitate insertion of the catheter within the urethra while also simplifying manufacture of the catheter.

An intraurethral catheter of the present invention comprises a shaft including an antenna lumen having a generally circular cross-sectional area for receiving a microwave antenna. The antenna lumen is positioned nearer a first side of the catheter shaft than a second side of the catheter shaft. The microwave antenna, when energized, produces a cylindrically symmetrical radiation pattern about the antenna.

A first and second pair of cooling lumens substantially surround the antenna lumen and have a generally arc shaped cross-sectional area configured to be circumjacent to the antenna lumen about a substantial majority of the antenna lumen. The second pair of cooling lumens have a cross-sectional area greater than the cross-sectional area of the first pair of cooling lumens. A urinary drainage lumen is positioned between the second pair of cooling lumens adjacent the antenna lumen and has a generally circular cross-sectional surface area.

The generally arc shaped cross-sectional surface area of the cooling lumens is configured to maximize exposure of the surface area of the cooling lumens to the antenna lumen. The generally arc shape of the cooling lumens places an inner wall of the cooling lumens immediately circumjacent a substantial majority of the antenna lumen. This configuration maximizes efficiency of the cooling lumens in counteracting heat generated by the microwave antenna in a region immediately surrounding the antenna and the catheter shaft.

The first pair of cooling lumens are positioned adjacent the first side of the catheter shaft while the larger second pair of cooling lumens are

positioned adjacent the second side. The larger, second pair of cooling lumens (when filled with fluid) absorb a greater amount of microwave energy than the first pair of cooling lumens to produce a preferential asymmetrical radiation pattern in the prostatic tissue being treated. In combination with the eccentric position of the antenna lumen, the cooling lumen configuration about the antenna lumen permits heating of prostatic tissue adjacent a first side of the catheter above 45°C to necrose tumorous tissue while maintaining tissue adjacent the second side below 45°C to preserve healthy tissue.

The generally circular cross-sectional surface area of the urinary drainage lumen is configured to minimize exposure of the surface area of the urinary drainage lumen relative to an antenna lumen also having a generally circular cross section. The generally circular cross-sectional shape of the urine drainage lumen places only a point of the circular lumen immediately adjacent the generally circular cross-section of the antenna lumen. The generally circular shape of the urinary drainage lumen and its placement relative to the antenna lumen reduces the effect that variability in urine flow has on the radiation pattern generated by the microwave antenna.

In addition, providing a urinary drainage lumen with a generally circular cross-sectional area greatly improves the likelihood of the lumen remaining open when a portion of the catheter shaft is positioned into a curved or bent position within the urethra. The generally circular cross section provides a shape that can remain open even if the catheter is bent in any one of several different directions.

The lumens of the catheter shaft are preferably defined by a unitary wall having a substantially uniform thickness throughout the catheter. However, a catheter of the present invention can further include a portion of the wall of the catheter having a thickness of about two times the substantially uniform wall thickness and defining a common wall of the antenna lumen and the temperature sensing lumen. In addition, a second portion of the wall of the

catheter can have a wall thickness of about one-half the substantially uniform thickness and define an outer wall of the temperature sensing lumen and the first outer surface of the catheter. This configuration maximizes insulation between a thermal sensing device positioned within the temperature sensing lumen and the microwave energy and heat generated by a microwave antenna positioned within the antenna lumen of the catheter shaft. This increases the accuracy of temperature measurements of the tissue surrounding the transurethral catheter.

A temperature sensing lumen of the transurethral catheter of the present invention can further include an elongate insert positioned alongside a thermal sensing device within the temperature sensing lumen between the thermal sensing device and the antenna lumen. This insert further insulates the thermal sensing device from the heat generated by the microwave antenna field and places the thermal sensing device closer to the prostatic tissue to further increase the accuracy of the thermal sensing device in measuring the temperature of the surrounding prostatic tissue. The insert also moves the thermal sensing device further away from the cooling fluid intake lumens thereby reducing the cooling effect of cooling fluids on temperature measurements taken by the thermal sensing device.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a vertical sectional view of a male pelvic region showing the urinary organs affected by benign prostatic hyperplasia.

Fig. 2 is a plan view of the urethral catheter of the present invention.

Fig. 3 is a cross-sectional view of the urethral catheter of Fig. 2 taken along line 3-3.

Fig. 4 is a cross-sectional view of the urethral catheter of Fig. 2 taken along line 4-4.

Fig. 5 is a perspective view of a proximal portion of the urethral catheter with the proximal end portion taken in section from line 5-5 of Fig. 2.

Fig. 6 is a perspective view of a combined tip and balloon of the urethral catheter of the present invention.

Fig. 7 is an enlarged sectional view of the proximal end of the urethral catheter of the present invention.

Fig. 8 is a partial sectional view of the temperature sensing lumen and an elongate insert of the urethral catheter of the present invention.

Fig. 9 is a cross-sectional view of the urethral catheter of Fig. 8 taken along line 9-9.

Fig. 10 is a cross-sectional view of an alternative embodiment of a tubular elongate insert of the present invention.

Fig. 11 is an enlarged view of the male pelvic region of Fig. 1 showing the urethral catheter of the present invention positioned within the prostate region.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Fig. 1 is a vertical sectional view of a male pelvic region showing the effect benign prostatic hyperplasia (BPH) has on the urinary organs. Urethra 10 is a duct leading from bladder 12, through prostate 14 and out orifice 16 of penis end 18. Benign tumorous tissue growth within prostate 14 around urethra 10 causes constriction 20 of urethra 10, which interrupts the flow of urine from bladder 12 to orifice 16. The tumorous tissue of prostate 14 which encroaches urethra 10 and causes constriction 20 can be effectively removed by heating and necrosing the encroaching tumorous tissue. Ideally, with the present invention, only periurethral tumorous tissue of prostate 14 anterior and lateral to urethra 10 is heated and necrosed to avoid unnecessary and undesirous damage to urethra 10 and to adjacent healthy tissues, such as ejaculatory duct 24 and rectum 26. A selective heating of benign tumorous tissue of prostate 14 (transurethral thermal therapy) is made possible by microwave antenna-containing catheter 28 of the present invention, which is shown in Fig. 2.

As shown in Fig. 2, catheter 28 generally includes multi-port manifold 30, multi-lumen shaft 32, and tip 34 which includes balloon portion 36, tip portion 38, and side port 39. Manifold 30 includes inflation port 40, urine drainage port 42, microwave antenna port 44, cooling fluid intake port 46, and cooling fluid exhaust port 48. Ports 40-48 of manifold 30 communicate with corresponding lumens within shaft 32. Manifold 30 is preferably made of medical-grade silicone sold by Dow Corning under the trademark Silastic® Q-7-4850.

Catheter 28 can be employed in a thermal therapy catheter system further including a cooling system, a microwave generating source, and a urethral thermometry unit. These additional elements of a thermal therapy catheter system are disclosed in Rudie et al. U.S. Patent No. 5,413,588, which is hereby incorporated by reference. In particular, manifold 30 of catheter 28 of the present invention cooperates with a transurethral thermal catheter system in the same manner that manifold 30 disclosed in the Rudie patent cooperates with the multi-lumen catheter, cooling system, microwave generating source, and transurethral thermometry unit disclosed in that patent. For instance, inflation port 40 of manifold 30 of the present invention is adapted for receiving an inflation fluid for inflating balloon 36. Urinary drainage port 42 of manifold 30 is adapted to facilitate urine from catheter shaft 32, and antenna port 44 is adapted to receive a microwave antenna for insertion and positioning within the multi-lumen catheter shaft 32. Cooling fluid intake port 46 and cooling fluid exhaust port 48 are cooperable with a cooling system for providing selective flow of cooling fluids within multi-lumen catheter shaft 32.

Shaft 32 is connected to manifold 30 at shaft distal end 50. Shaft 32 is long enough to permit insertion of balloon 36 through urethra 10 and into bladder 12. Shaft 32 is a multi-lumen urethral catheter shaft which is extruded from a flexible, medical-grade silicone sold by Dow Corning under the

trademark Silastic® Q-7-4850. The silicone material preferably has a durometer hardness of 80 Shore A.

As shown in Fig. 3, multi-lumen shaft 32 includes temperature sensing lumen 56, microwave antenna lumen 58, urine drainage lumen 60, balloon inflation lumen 62, cooling fluid intake lumens 64A and 64B, and cooling exhaust lumens 66A and 66B. Lumens 56-66B generally extend from distal shaft end 50 to proximal shaft end 54. Lumens 56-66B are defined by unitary wall 68 which has a substantially uniform thickness throughout a cross section of catheter shaft 32. Catheter wall 68 preferably has a thickness of 0.009 inches. A center of each of lumens 56-62 is aligned along a longitudinal axis of an elliptical cross section of catheter shaft 32. Protective sheath 71 covers outer surface 52 of catheter shaft 32 and is preferably made of Teflon® to facilitate its advancement within urethra 10.

Temperature sensing lumen 56 is positioned near first side 70 of shaft 32. Temperature sensing lumen 56 has a generally circular cross sectional surface area and is configured to permit insertion of a thermometry sensor within shaft 32 to monitor the temperature of surrounding prostatic tissue when shaft 32 is inserted within urethra 10. Temperature sensing lumen 56 preferably has a diameter of about 0.032 inches.

First modified portion 72 of catheter wall 68 defines a common wall between antenna lumen 58 and temperature sensing lumen 56. First modified wall portion 72 preferably has a thickness (e.g., 0.020 inches) about two times the otherwise substantially uniform thickness of catheter wall 68. Second modified portion 74 of catheter wall 68 defines an outer wall of temperature sensing lumen 56 and preferably has a thickness (e.g., 0.005 inches) about one-half the otherwise substantially uniform wall thickness of catheter wall 68.

Microwave antenna lumen 58 is positioned eccentric to the longitudinal axis of catheter shaft 32, antenna lumen 58 being positioned nearer

first side 70 of shaft 32 than second side 76 of shaft 32. Microwave antenna lumen 58 preferably has a generally circular cross-sectional surface area which is larger than a cross-sectional surface area of any of the other respective lumens of catheter shaft 32. Antenna lumen 58 preferably has a diameter of about 0.106 inches. At its distal end, antenna lumen 58 communicates with microwave antenna port 44 of manifold 30. Antenna lumen 58 is adapted for receiving a microwave antenna to be permanently positioned within antenna lumen 58 of shaft 32 near balloon 36 (Fig. 2) so the antenna will be generally situated adjacent benign tumorous tissue of prostrate 14 when shaft 32 is properly positioned within urethra 10. A microwave antenna suitable for incorporation into catheter 28 of the present invention is disclosed in Rudie et al. U.S. Patent No. 5,413,588, issued May 9, 1995, and is hereby incorporated by reference.

Urine drainage lumen 60 is positioned adjacent antenna lumen 58 between antenna lumen 58 and second side 76 of shaft 32. Urine drainage lumen 60 has a generally circular cross-sectional surface area defined by catheter wall 68 and preferably has a diameter of about 0.04 inches. Urine drainage lumen 60 communicates with urine drainage port 42 of manifold 30 at distal shaft end 50 and with tip 34 at proximal shaft end 54 to define a drainage path for urine when tip 34 of catheter 28 is inserted within bladder 12. Urine flows into tip 34 through side port 39 (Fig. 2). Drainage of urine from bladder 12 is necessary due to frequent bladder spasms which occur during transurethral thermal therapy.

Balloon inflation lumen 62 is positioned near second side 76 of shaft 32, generally between urine drainage lumen 60 and second side 76. Balloon inflation lumen 62 preferably has a generally circular cross-sectional surface area defined by catheter wall 68 and preferably has a diameter of about 0.04 inches. Balloon inflation lumen 62 communicates with inflation port 40 of manifold 30 for moving balloon inflation fluid in and out of the balloon

inflation lumen 62. Balloon inflation lumen 62 is provided for supplying an inflation fluid to balloon portion 36 of tip 34.

Cooling fluid intake lumens 64A and 64B are positioned circumjacent antenna lumen 58 and first side 70, being located between first side 70 and antenna lumen 58. Cooling fluid intake lumens 64A and 64B are defined by single unitary catheter wall 68 and preferably have a generally arc shaped cross-sectional surface area configured to partially surround antenna lumen 58. Cooling lumens 64A and 64B also preferably have a uniform radial thickness. Cooling fluid intake lumens 64A and 64B extend from distal shaft end 50 to proximal shaft end 54. Fluid contained within intake lumens 64A and 64B absorbs a portion of microwave energy emitted by a microwave antenna within antenna lumen 58 to control the volume of prostatic tissue adjacent first side 70 of shaft 32 that is heated above 45°C. Water within intake lumens 64A and 64B also absorbs heat energy generated by microwave energy from adjacent tissues via thermal conduction. Cooling fluid intake lumens 64A, 64B have a radial thickness of about 0.028 inches and have an inner radius of 0.062 inches and an outer radius of 0.09 inches (relative to a focus of the elliptical cross-section of shaft 32 nearest first side 70).

Cooling fluid exhaust lumens 66A and 66B are generally positioned between second side 76 and antenna lumen 58 and have a generally arc-shaped cross-sectional surface area. First portions 67A and 67B of cooling exhaust lumens 66A and 66B are circumjacent antenna lumen 58 and second portions 69A and 69B are circumjacent second side 76 of catheter shaft 32. The generally arc shaped cross-sectional surface area of cooling fluid exhaust lumens 66A and 66B is modified to accommodate the presence of urine drainage lumen 60 between cooling exhaust lumens 66A and 66B. Cooling exhaust lumens 66A and 66B extend from shaft distal end 50 to shaft proximal end 54. Cooling exhaust lumens 66A and 66B are wider in cross section than cooling intake lumens 64A and 64B and have a cross-sectional surface area greater than the

cross-sectional surface area of cooling intake lumens 64A and 64B. Cooling fluid exhaust lumens 66A, 66B have an outer radius of 0.09 inches (relative to a focus of the elliptical shaft cross section of shaft 32 nearest first side 70). Portion 67A, 67B of lumens 66A, 66B have an inner radius of 0.062 inches (relative to the focus of the elliptical shaft cross section nearest first side 70).

This greater cross-sectional surface area of exhaust lumens 66A and 66B enable water within exhaust lumen 66A and 66B to be capable of absorbing a greater amount of microwave energy when a microwave antenna disposed within antenna lumen 58 is energized. Given the power output currently used with a microwave antenna such as that disclosed in Rudie et al. U.S. Patent No. 5,413,588, the temperature of tissue adjacent second side 76 of shaft 32 will remain below about 45°C. This prevents the portion of urethra 10 adjacent second side 76 from being overheated and damaged when a microwave antenna within antenna lumen 58 is energized.

Cooling intake lumens 64A and 64B and exhaust lumens 66A and 66B cooperate with a cooling system via ports 46 and 48 of manifold 30 to provide a selectively controlled flow of fluid through cooling lumens 64A, 64B, 66A, and 66B during a treatment session. This arrangement achieves a desired cooling pattern surrounding a microwave antenna energized within antenna lumen 58 while catheter shaft 32 is within a urethra 10. Cooling intake lumens 64A, 64B and cooling exhaust lumens 66A, 66B can be used with a cooling system under the treatment parameters as described in Rudie et al. U.S. Patent No. 5,413,588, (earlier incorporated by reference) and under the treatment parameters disclosed in pending application U.S. Serial No. 08/309,137, filed September 20, 1994.

Cooling fluid intake lumens 64A and 64B are in communication with cooling exhaust lumens 66A and 66B, respectively, near proximal shaft end 54 of catheter shaft 32 adjacent balloon portion 36 (Fig. 2). As shown in Fig. 4, a portion of catheter wall 68 defining a common wall between cooling intake

lumen 64A and cooling exhaust lumen 66A has been removed creating hole 77A to permit communication between the respective lumens. Similarly, a portion of catheter wall 68 defining a common wall between cooling intake lumen 64B and cooling exhaust lumen 66B has been removed creating hole 77B to allow communication between the respective lumens 64B and 66B. This configuration permits cooling fluid that is flowing proximally through cooling intake lumens 64A and 64B to enter cooling exhaust lumens 66A and 66B, respectively, to establish a cooling fluid flow loop that cooperates with a cooling system connected to manifold 30.

Fig. 5 illustrates a cross section of catheter shaft 32 adjacent a shaft end 54 just proximal to balloon 36 (see Fig. 2). At this location, temperature sensing lumen 56, antenna lumen 58, inflation lumen 62, cooling intake lumens 64A and 64B, and cooling exhaust lumens 66A and 66B are closed by silicone plug material 78 sealing each of these lumens at proximal shaft end 54. However, urine drainage lumen 60 remains open at proximal shaft end 54 so that urine from the bladder may pass through tip 34 and into urine drainage lumen 60.

As shown in Fig. 6, tip 34 comprises a single unitary member including balloon portion 36 and tip portion 38. Balloon portion 36 is a flexible tubular portion having distal end 80, proximal end 82, side wall 84, inner surface 86, ribs 88, and hole 90. Side wall 84 of tubular balloon portion 36 extends between distal end 80 and proximal end 82 and has inner surface 86 with ribs 88 formed thereon extending circumferentially on the inner surface 86. Ribs 88 are visible in Fig. 6 since flexible tubular portion of balloon portion 36 is preferably made from a translucent material. Side wall 84 of tubular balloon portion 36 includes hole 90 formed adjacent proximal end 82.

Tip portion 38 comprises a flexible curved body having distal end 92, proximal tip end 94, tip lumen 96, dividing wall 98, and hole 100. Tip lumen 96 extends through a portion of the tip body and communicates with side

port 39. Side port 39 permits insertion of a guide wire (not shown) into tip lumen 96 to facilitate insertion of intraurethral catheter 28 within urethra 10 in a manner well known in the art. Dividing wall 98 at distal end 92 defines a border between balloon portion 36 and tip portion 38. Wall 98 also defines a distal end of tip lumen 96 and has hole 100 formed therein to permit communication between tip lumen 96 and an interior of tubular balloon portion 36.

Tip 34 is formed by liquid injection molding from a flexible, medical-grade silicone sold by Dow Corning under the trademark Silastic® Q-7-4850. The silicone preferably has a material hardness of 20 Shore A, which is relatively soft to provide an atraumatic tip. Tip 34 can also include a radiopaque filler such as barium sulfate added to the silicone material to make tip 34 observable under fluoroscopy.

Tip 34 preferably has a length of 1.95 inches including tip portion 38 which preferably has a length of 0.84 inches. Tubular portion 36 preferably has a length of 1.11 inches including the ribbed portion which has a length of 0.64 inches. Side wall 94 preferably has a thickness of 0.01 inches while ribs 88 preferably have a radius of 0.01 inches and are spaced longitudinally with respect to each other by 0.16 inches. Tubular portion 36 has an elliptical cross section and has a radius of about 0.110 inches, wherein the foci of the ellipse are separated by 0.053 inches. Side wall 94 of tubular portion is capable of elongating up to 400% so that an elliptical cross section of balloon portion 36 when expanded has a cross sectional area about 4 times its cross sectional area in a nonexpanded state.

Fig. 7 provides a more detailed view of catheter shaft 32 and tip 34 at proximal shaft end 54. Proximal shaft end 54 of catheter 28 fits snugly within tubular portion 36 of tip 34 with utmost proximal shaft end 54 resting against dividing wall 98 of tip 34 and outer surface 52 of catheter shaft 32 in

contact with multiple structures defining an interior of tubular balloon portion 36.

As shown in FIG. 7, urine drainage lumen 60 further includes expanded diameter portion 102 while inflation lumen 62 further includes hole 104. Temperature sensing lumen 56, antenna lumen 58, and inflation lumen 62 further include silicone plug material 78 filled within their proximal ends. Balloon portion 36 of tip 34 further includes first collar 106, second collar 108, first well 110, second well 112, third well 114, adhesive dam 116, first rib 118, and second rib 119.

Expanded diameter section 102 of urine drainage lumen 60 has a generally conical shape and communicates with tip lumen 96 via hole 100 in wall 98 to permit urine flow therethrough. Hole 104 of inflation lumen 62 permits communication between inflation lumen 62 and an interior of balloon portion 36 for inflating and deflating balloon portion 36.

Expanded diameter portion 102 of urine drainage lumen 60 is formed at the time silicone plug material 78 is introduced into the other lumens 32 at proximal shaft end 54. In particular, a syringe tip is introduced into urine drainage lumen 60 at proximal shaft end 54 and maintained in that position while silicone plug material 78 is introduced into all of the remaining lumens defining catheter shaft 32. The introduction of silicone plug material 78 includes the application of heat to proximal shaft end 54, thereby causing urinary drainage lumen 60 to permanently expand and reform about the shape of the syringe tip. Upon setting of the silicone plug material 78, the syringe tip is removed from proximal shaft end 54 resulting in urine drainage lumen 60 having expanded diameter portion 102 and each of the other respective lumens of catheter shaft 32 having sealed ends filled with silicone plug material 78.

First collar 106 of balloon portion 36 defines distal end 80 while second collar 108 defines proximal end 82 with side wall 84 extending therebetween. First well 110 defines a reservoir formed between first collar

106, first rib 118, and side wall 84 while second well 112 defines a reservoir formed between second collar 108, side wall 84, and adhesive dam 116. Third well 114 defines a reservoir formed between adhesive dam 116, side wall 84, and second rib 119.

To secure tip 34 onto proximal shaft end 54, tubular portion 36 is slip fit over proximal shaft end 54 into the position shown in FIG. 7. Next, tubular portion 36 is secured about proximal shaft end 54 with an adhesive. Adhesive is introduced between first collar 106 and shaft outer surface 52 of shaft 32 to create a sealed connection therebetween. First well 110 catches any excess adhesive that wicks proximally beyond first collar 106.

Side hole 90 is used to introduce adhesive between second collar 108 and shaft outer surface 32 at utmost shaft proximal end 54. Second well 112 receives adhesive introduced through side hole 90 while adhesive dam 116 blocks adhesive from migrating distally toward inner surface 86 of side wall 84. Third well 118 acts as an additional reservoir for catching excess adhesive migrating past adhesive dam 116.

With first collar 106 and second collar 108 of tubular portion 36 sealingly connected about shaft outer surface 52, side wall 84 remains free to expand relative to shaft outer surface 52 upon introduction of inflation fluid within an interior of balloon portion 36 (via inflation lumen 62 through hole 104). Ribs 88 remain spaced slightly from outer surface 52 and maintain spacing between inner surface 86 of side wall 84 and outer surface 52 of catheter shaft 32. This prevents the silicone material forming balloon portion 36 from sticking to the silicone material forming shaft outer surface 52. In the absence of ribs 88, inner surface 86 of side wall 84 would tend to stick to shaft outer surface 52 and thereby inhibit inflation and expansion of side wall 84.

Tubular portion 36 is positioned on proximal shaft end 54 so that side wall 84 can be expanded within bladder 12 to maintain a proximal end of a microwave antenna (within catheter shaft 32) spaced at least 4 millimeters

proximally from the opening of the bladder 12. This positions the microwave antenna within urethra 10 so that healthy prostatic tissue between a tip of the microwave antenna and bladder 12 is preserved.

As shown in Fig. 8, an alternative embodiment of catheter shaft 32 further includes elongate insert 120. Elongate insert 120 includes first end 122 and second end 124. Elongate insert 120 is positioned within temperature sensing lumen 56 alongside sensor 126 of thermal sensing device 128 adjacent microwave antenna 130 positioned within antenna lumen 58. Elongate insert 120 displaces sensor 126 of thermal sensing device 128 radially away from antenna 130 and toward first side 70 of catheter shaft 32.

Fig. 9 illustrates a cross-sectional view of elongate insert 120. Elongate insert 120 has a generally crescent shaped cross-sectional surface area including a concave surface and has a width approximately one-half the diameter of temperature sensing lumen 56. Concave surface 127 of elongate insert 120 is positioned circumjacent sensor 126 between thermal sensing device 128 and antenna lumen 58 to move sensor 126 within temperature sensing lumen 56 as far away as possible from microwave antenna 130 and cooling lumens 64A and 64B. This arrangement increases the accuracy of temperature measurements of surrounding prostatic tissue adjacent shaft first side 70 by better insulating sensor 126 from both heating (microwave antenna) and cooling (cooling fluid) sources within catheter shaft 32. Elongate insert 120, in filling up a portion of the cross sectional area within temperature sensing lumen 56, effectively eliminates excess spacing within lumen 56 that is necessary to permit insertion of thermal sensing device 128 within lumen 56.

Elongate insert 120 can be inserted into temperature sensing lumen 56 either before or after thermal sensing device 128 is positioned within temperature sensing lumen 56. Elongate insert 120 is introduced into temperature sensing lumen 56 by making a cut in first side 70 of catheter shaft 32 adjacent temperature sensing lumen 56 and advancing elongate insert 120

distally through temperature sensing lumen 56 until elongate insert 120 is completely within temperature sensing 56 and resting on an inner wall of temperature sensing lumen 56. Elongate insert 120 is then held in place against the inner wall of temperature sensing lumen 56 until sensor 126 is properly positioned relative to elongate insert 120. Thereafter, the slit made in first side 70 of catheter shaft 32 is sealed using an adhesive filler. Elongate insert 120 has a length of about one to two inches, a thickness at its center of about 0.013 inches, and a width between its outer edges of about 0.32 inches. Elongate insert 120 is preferably formed from a Teflon® material to facilitate sliding movement of sensor 126 relative to insert 120.

As shown in Fig. 10, tubular elongate insert 140 provides an alternative embodiment to crescent shaped elongate insert 120. Tubular elongate insert 140 includes inner surface 142, outer surface 144 and wall 146 defined therebetween. Tubular insert 140 is positioned within temperature sensing lumen 58 and surrounds sensor 126 of thermal sensing device 128. Like elongate insert 120, tubular insert 140 displaces sensor 126 away from antenna 130 and cooling lumens 64A and 64B toward first side 70 of catheter shaft 32, thereby eliminating excess space within temperature sensing lumen 58 and increasing the accuracy of temperature measurements of the surrounding prostatic tissue.

Tubular insert 140 is placed within temperature sensing lumen 58 according to the insertion method described for elongate insert 120. Tubular insert 140 is preferably formed from a Teflon® material to facilitate sliding movement of sensor 126 relative to tubular insert 140. Tubular insert 140 has a length of about one to two inches, wall 146 has a uniform radial thickness of about 0.007 inches, and outer surface 144 has a diameter of about 0.032 inches.

In use, catheter 28 of the present invention including multi-lumen catheter shaft 32 and tip 34 including balloon portion 36 is employed according to the insertion method and treatment method described in Rudie et al. U.S.

Patent No. 5,413,588. Additional urethral treatment parameters can be employed with catheter 28 of the present invention such as that described in U.S. Patent Application Serial No. 08/309,137 filed September 20, 1994 and hereby incorporated by reference.

Fig. 11 shows an enlarged view of the male pelvic region of Fig. 1 with catheter 28 properly positioned within urethra 10. Shaft 32 is positioned within urethra 10 with second side 76 of shaft 32 oriented toward rectum 26. Cooling fluid exhaust lumens 66A, 66B are oriented posteriorly, toward rectum 26 and cooling fluid intake lumens 64A, 64B are oriented anteriorly toward fibromuscular tissue 140 of prostate 14. The portion of transition zone 142 anterior and lateral to urethra 10 is the most frequent location of the tumorous tissue growth which causes BPH. Since cooling fluid exhaust lumens 66A, 66B are capable of absorbing more microwave energy than cooling fluid intake lumens 64A, 64B, the radiation patterns created by microwave energy emitted from antenna 144 are asymmetrical. Thus, a relatively large volume of tissue enveloping the anterior portion of transition zone 142, adjacent first side 70, is heated to a temperature above about 45°C, which effectively necroses the tumorous tissue of prostate 14 which encroaches upon urethra 10. In comparison, the temperature of tissue adjacent second side 76 remains below about 45°C, thereby eliminating the harmful effects of the microwave energy to ejaculatory duct 24 and rectum 26.

Catheter 28 of the present invention including multi lumen shaft 32 and tip 34 yield numerous advantages over the prior art. First, multi lumen catheter shaft 32 is configured to maximize exposure of its cooling lumens to an antenna lumen carrying a microwave antenna. This optimized configuration is established by having cooling fluid intake and exhaust lumens with a generally arc shaped cross-sectional area which substantially surround an antenna lumen having a generally circular cross-sectional area. These lumens are defined by a unitary wall having a substantially uniform wall thickness arranged to

maximize the cross-sectional surface area of the cooling lumens relative to the antenna lumen. Second, a urine drainage lumen of the present invention has a generally circular cross-sectional surface area which tends to remain open even when an intraurethral catheter of the present invention is disposed within a portion of a urethra which bends the intraurethral catheter. In addition, the generally circular cross-sectional area of the urine drainage lumen disposed adjacent the antenna lumen minimizes the relative surface area and exposure between the urine drainage lumen and the antenna lumen. This reduces the effect that variable urine flow within the urine drainage lumen has on microwave antenna tuning and on the consistency of the shape and energy of a microwave radiation pattern generated by the microwave antenna within the antenna lumen.

Finally, the lumens of multi lumen catheter shaft 32 are arranged and shaped to increase the structural integrity of catheter shaft 32 while maximizing the surface area of each of the respective lumens. This is accomplished by defining the respective lumens by a single unitary wall having a substantially uniform wall thickness and by selecting optimal shapes of the cross-sectional surface area of the lumens.

The tip 34 of catheter 28 of the present invention also has numerous advantages. First, a tip comprising a single unitary member including an insertion tip and an inflatable balloon portion greatly simplifies assembly of the catheter. The tip can simply be slip fit over a proximal end of the catheter shaft and secured thereto with an adhesive. The insertion tip portion facilitates insertion and guidance of the catheter of the present invention within the urethra. A balloon of a tip of the present invention is constructed to maintain a low profile in its deflated state to facilitate insertion and passage of the catheter within a urethra. Unlike prior art balloon designs, a balloon of a tip of the present invention does not have any excess material or winged portions which must be folded down or compressed during insertion of or passage of the

balloon through the urethra. Rather, the unique structure of a balloon of the tip of the present invention yields a balloon which remains relatively flat in its deflated state during passage through the urethra. A tubular portion comprising a balloon of the present invention is arranged and configured to facilitate introducing adhesive for sealing the balloon about an outer surface of the catheter shaft without compromising an effective length of the inflatable portion of the balloon caused by wicking of the adhesive toward an anterior portion of the balloon.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An intraurethral catheter comprising:

an elongate shaft having a first end, a second end, a first outer surface, and a second outer surface, the shaft further comprising:

a plurality of lumens which extend between the first end and the second end of the shaft including,

an antenna lumen having a generally circular cross-sectional surface area and being positioned nearer the first outer surface than the second outer surface;

a first pair and a second pair of cooling lumens substantially surrounding the antenna lumen wherein the cooling lumens have a generally arc shaped cross-sectional surface area are configured to be adjacent to the antenna lumen about a substantial majority of the antenna lumen; and

a urinary drainage lumen positioned between the second pair of cooling lumens adjacent the antenna lumen, the urinary drainage lumen having a generally circular cross-sectional surface area.

2. The catheter of claim 1 and further comprising:

a temperature sensing lumen positioned between the first outer surface and the antenna lumen and having a generally circular cross-sectional surface area; and

an inflation lumen positioned between the second outer surface and the urinary drainage lumen and having a generally circular cross-sectional surface area.

3. The catheter of claim 2, and further comprising a thermal sensing device, the thermal sensing device being positioned within the temperature sensing lumen of the shaft.

4. The catheter of claim 3 and further comprising:

an elongate insert positioned within the temperature sensing lumen alongside the thermal sensing device between the thermal sensing device and the antenna lumen.

5. The catheter of claim 4 wherein the insert has a generally arcuate cross-sectional surface area and a concave surface of the insert is adjacent to the thermal sensing device.

6. The catheter of claim 3 and further comprising:

a tubular elongate insert positioned within the temperature sensing lumen and surrounding the thermal sensing device.

7. The catheter of claim 2 wherein the lumens of the catheter are defined by a single unitary wall having a substantially uniform thickness throughout the catheter.

8. The catheter of claim 1, and further comprising a heating device, the heating device being positionable within the antenna lumen of the shaft.

9. The catheter of claim 1 wherein a portion of the second pair of cooling lumens has a radial thickness about two times the radial thickness of the first pair of cooling lumens.

10. An intraurethral catheter comprising:

an elongate shaft having a first end, a second end, a first outer surface, a second outer surface, and a plurality of lumens which extend between the first end and the second end of

the shaft, the lumens being defined by a unitary wall having a substantially uniform wall thickness, and the shaft further comprising:

an antenna lumen having a generally circular cross-sectional surface area, wherein the antenna lumen is oriented nearer the first outer surface than the second outer surface; and

a first and second pair of cooling lumens and a urinary drainage lumen arranged to substantially surround the antenna lumen wherein an inner wall of the cooling lumens and the urinary drainage lumen are common with a wall defining the antenna lumen so that each of the cooling lumens and the urinary drainage lumen are spaced from the antenna lumen by no more than the substantially uniform wall thickness.

Fig. 1

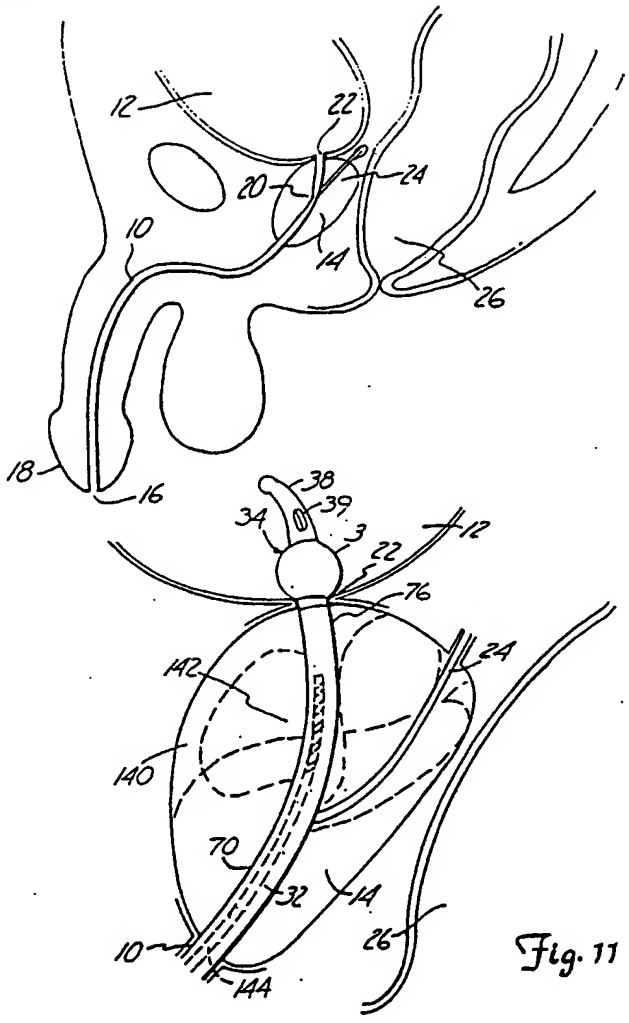

12
22
24
20
10
14
26
18
16
38
39
34
3
12
22
76
24
142
140
70
32
14
26
10
144

Fig. 11

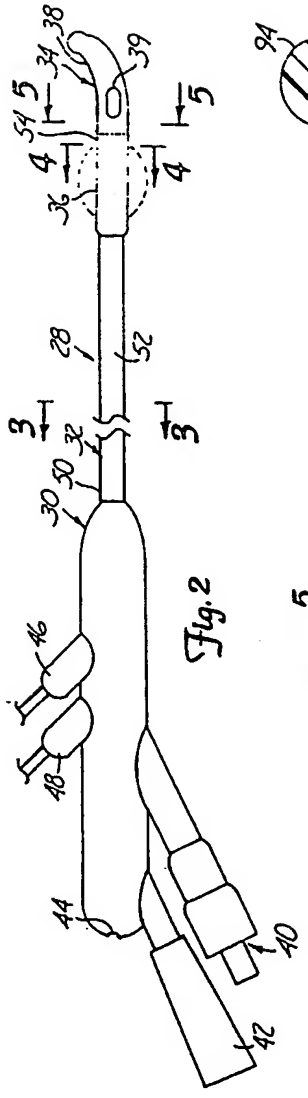

38
39
34
5
5
4
4
36
28
52
3
3
32
50
30
46
48
44
40
42

Fig. 2

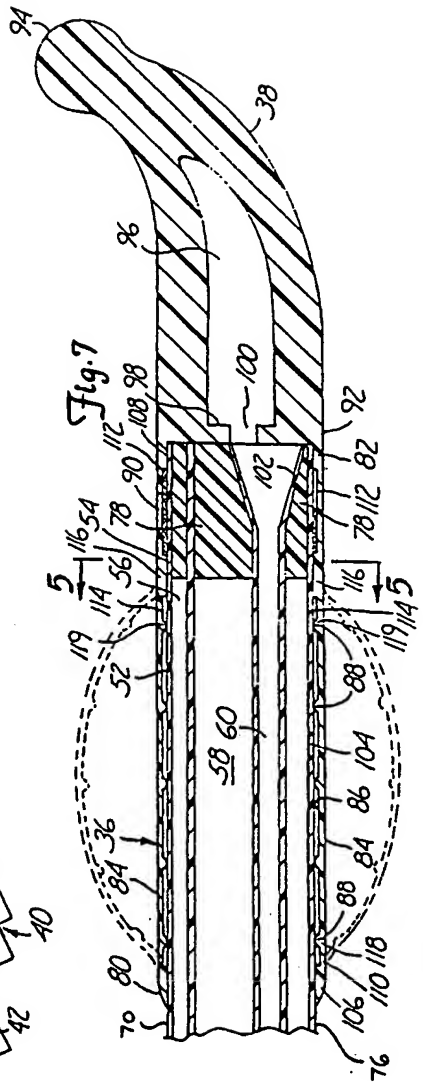

94
38
96
100
98
108
112
92
102
90
82
78
112
54
116
78
5
56
114
116
5
119
119
114
52
88
58
60
104
86
36
84
84
88
80
118
110
106
70
76

Fig. 7

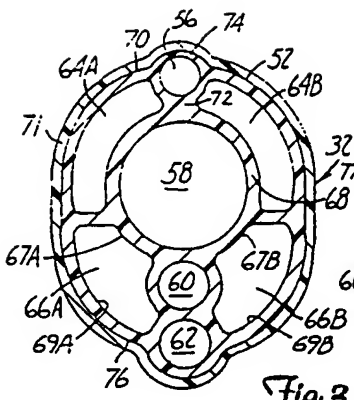


Fig. 3

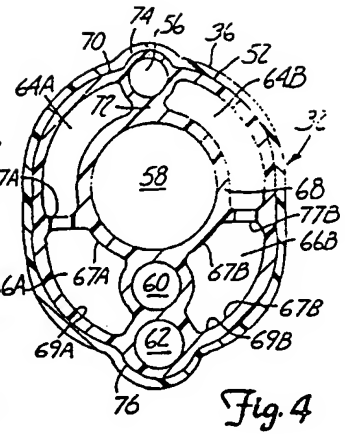


Fig. 4

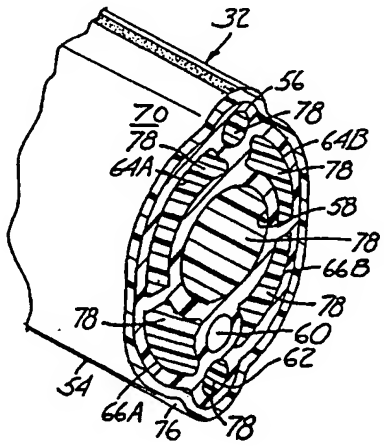


Fig. 5

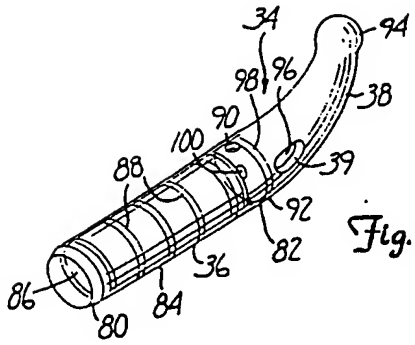
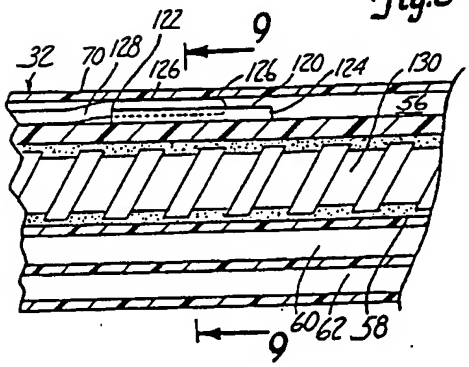


Fig. 6

Fig. 8



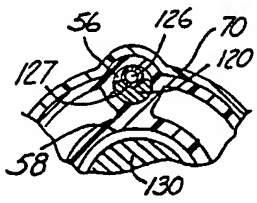


Fig. 9

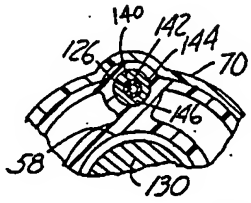


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/07878

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61N 5/02

US CL :607/101, 102, 105, 113, 156

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96-98; 607/101-105, 113, 156

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,413,588 (RUDIE ET AL.) 09 May 1995. see entire document.	1-10
Y, P	US, A, 5,464,437 (REID ET AL.) 07 November 1995, see entire document.	1-10
Y	US, A, 5,234,004 (HASCOET ET AL.) 10 August 1993, see entre document.	4-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 01 JULY 1996	Date of mailing of the international search report 08 AUG 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer HERMAN J. ROBINSON Telephone No. (703) 308-2909

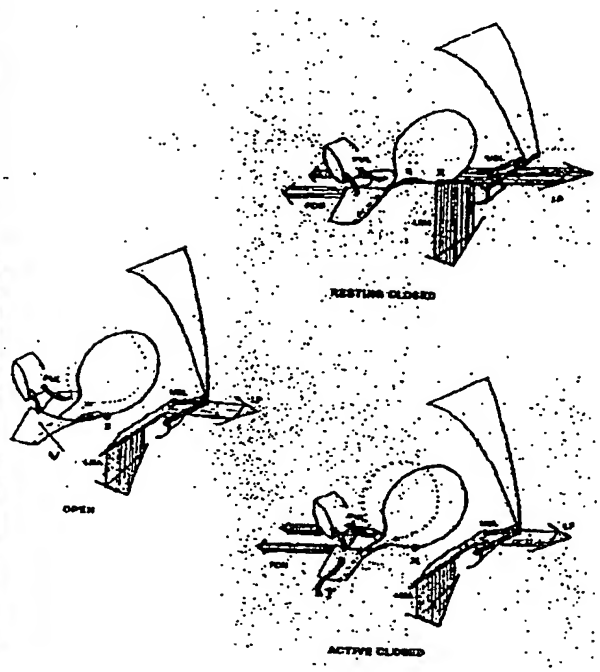
Form PCT/ISA/210 (second sheet)(July 1992)*

CA

ISSN 0300-8886

Scandinavian Journal of **Urology and Nephrology**

Supplement 153: 1993



AN INTEGRAL THEORY AND ITS METHOD FOR THE DIAGNOSIS AND MANAGEMENT OF FEMALE URINARY INCONTINENCE

by PE Papa Petros and U Ulmsten

SCANDINAVIAN JOURNAL OF UROLOGY AND NEPHROLOGY SUPPLEMENT No. 153

AN INTEGRAL THEORY AND ITS METHOD FOR THE DIAGNOSIS AND MANAGEMENT OF FEMALE URINARY INCONTINENCE

PETER E PAPA PETROS

ULF I ULMSTEN

P.E. PAPA PETROS Dr Med Sc MRCOG FRACOG
Department of Gynaecology
Royal Perth Hospital
Perth, Western Australia
Department of Obstetrics and Gynaecology
Uppsala University
Akademiska sjukhuset
Uppsala, Sweden.

U. ULMSTEN M. D. Ph.D.
Department of Obstetrics and Gynaecology
Uppsala University
Akademiska sjukhuset
Uppsala, Sweden.

Supported by research grants from
Swedish Medical Council No.s 8310 and 3495
Goran Gustaffson's Foundation
and Royal Perth Hospital

ISSN No. 0300-8886

CONTENTS

ACKNOWLEDGEMENTS

We would like to thank Ms Carol Yelas and Ms Marie Lindström, and also, the Depts of Radiology and Medical Illustration Royal Perth Hospital, for their assistance with preparation of the text and figures of the manuscript. We are also indebted to Dr Kate Creed. Professors Per Johnson, Anders Malmström, Anders Mattiasson, to Dr Richard Fox, Ed Skull, David Guy from the Dept of Medical Physics and Bioengineering, Royal Perth Hospital, for fruitful discussions and invaluable advice and to Professor Stig Colleen for editorial assistance.

The investigations were supported by grants from the Swedish Medical Research Council, No 8310 and No 3495, from Göran Gustafssons Foundation and from the Medical Faculty, Uppsala University and Royal Perth Hospital.

FOREWORD

It is now almost 3 years since we presented our Integral Theory of Female Urinary Incontinence (1). Since that time we have had the opportunity to challenge the concepts originally presented, not only by further morphological and urodynamic studies, but in a clinical sense also, by direct application of the theory to each of the hundreds of patients we have treated in that time. This has led to many of the concepts being further refined and clarified. In the present work, many of the muscle movements predicted by the theory have been identified using levator myograms, barium studies, EMG and pressure studies. We introduce a new concept for dynamic pressure measurements in the urethra and bladder, whereby pressure transmission ratio reflects directly the contractile force of the pelvic floor, and indirectly, specific defects in the vagina or its supporting ligaments.

Style of Expression

In this work, we have attempted to fulfil the criteria of Karl Popper as concerns expression and exposition of a theory. Therefore the Integral Theory has been deliberately expressed in a small number of explicit statements. This fulfils a prime obligation of any theory, that it must be testable for truth or falsity. This obligation has forced us to make many definitive statements on matters which have not been properly tested. This may reasonably irritate some readers. As medical scientists, we fully acknowledge this criticism. The alternative, however, would be to express the theory in a way which precludes proper testing of the theory. Explicit statements allow deductive methods of proof to be applied, and predictions to be made. This not only permits the theory itself to be tested by particular experiments, *but it also places an obligation on the theory to explain the large body of data already in existence. According to Popper, no theory can ever be finally proven.* In this context, this work can only be regarded as a small step in what we foresee will be a new perspective on female urinary incontinence.

Practical information and guidelines for reading this supplement.

This supplement is divided into four parts.

Part I gives an introduction of the integral theory on female urinary incontinence. Morphological, radiographic and urodynamic evidence is presented for the suggested mechanisms. The clinical perspective is given through six identified anatomical defects which also comprise a new classification for diagnosis and treatment of female urinary incontinence. Although somewhat detailed, this part constitutes a basic platform for the three sections which follow.

Part II aims to outline how the biochemical changes inherent in connective tissue affect the biomechanical properties of the vagina and its supporting ligaments, and how these in turn impact on functional and dysfunctional opening and closure of urethra and bladder neck.

Part III outlines briefly the surgical principles deriving from the integral theory as described in the two previous sections.

Part IV gives some direct surgical applications of the theory, based on parts I-III and also, our previous experimental work for treatment of female urinary incontinence (1). **Because the ultimate perspective of this work is therapeutic, we suggest that it may be useful to begin at section IV, and to work back at the reader's convenience.**

PE PAPA PETROS AND U ULMSTEN

(1) A detailed account of the original theory, its surgical applications, and various supporting clinical papers is available in Acta Scand O&G, Vol 69 Supplementum, No 153, 1990. 1-79. For the reader's convenience, exact page numbers are given along with this reference.

ORIGINAL ARTICLE

PART I: THEORETICAL, MORPHOLOGICAL, RADIOGRAPHICAL CORRELATIONS AND CLINICAL PERSPECTIVE

PE PAPA PETROS Dr Med Sc MRCOG FRACOG and U ULMSTEN MD PhD

ABSTRACT The Integral Theory on Female Urinary Incontinence states: stress symptoms, urge symptoms, and symptoms of defective flow may all derive , for different reasons, from laxity in the suburethral vagina or its supporting ligaments. This theory proposes that the pre-tensioned anterior vaginal wall transmits specific pelvic muscle contractions which open or close the bladder neck and urethra. The vagina is tensioned like the membrane of a drum against the ligaments which support it from above. In its tensioned state, the vagina can be pulled by the pelvic floor muscles to mechanically open or close bladder neck. The tensioned vagina also indirectly supports the nerve terminals at bladder base. Vaginal laxity may predispose to premature activation of the micturition reflex. If this reflex cannot be suppressed, then the subsequent uninhibited detrusor contraction may cause urinary urge incontinence (bladder instability). Therefore, laxity* in the vaginal tissue or its supporting ligaments may, for different reasons cause symptoms of stress incontinence, urge incontinence, or of defective opening.

Based on the evidence presented here and in previous studies (1), a new anatomical classification of female urinary incontinence can be made, consisting of six specific anatomical defects. Characteristic clinical, morphological and urodynamic changes which help to diagnose a particular defect are identified, as is the modifying effect of age, hormones, and iatrogenically induced scar tissue. Three separate closure mechanisms are described, urethral, bladder neck, and a separate voluntary mechanism.

* excessive tightness of these structures may also cause dysfunction of the opening/closure mechanisms in the patient who has been already subjected to surgical interference.

Key words: Theory; Urinary Incontinence; Connective Tissue; Biomechanics; Pelvic Floor; Surgery.

Review of existing theories of stress incontinence. It is a traditional concept in medicine, that dysfunction may be due to anatomical defects, and that function comes with restoration of anatomy. This has led to the identification of various morphological defects as causative factors for stress urinary incontinence (SI). These include the posterior urethrovesical angle (2), inclination of the urethral axis (3), (4), length of urethra (5) the relationship of urethrovesical junction to the most dependent part of bladder (6), flatness of the base plate (7), and anterior and posterior radiological defects of bladder base (8), pubourethral ligament (9) (10), paravaginal and other fascial defects, (11) (12). Due to a wide overlapping in the findings of continent and stress incontinent females, these morphological defects have been shown to bear little relationship to the existence of SI in a particular patient (13).

The most commonly accepted theory today (13) is the intra-abdominal pressure equalization theory, (14). And yet major inconsistencies have been present in this theory for a long time, FIG 1.

As early as 1954, Bailey (3) described his type 2B incontinence, whereby the bladder neck was situated high above the inferior border of pubic symphysis, with no significant rotation or descent on straining. Using simultaneous urethrocystometry, Constantinou (15) demonstrated that on coughing, the urethral

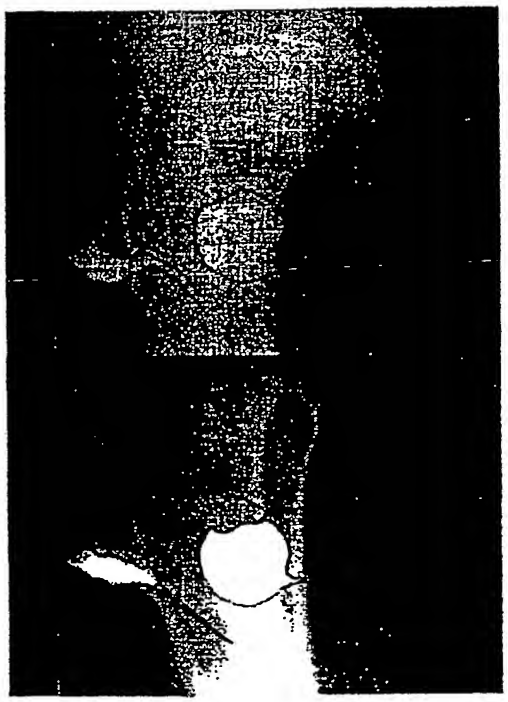


FIG 1
Inadequacy of pressure equalization theory.
F = Foley balloon; V = vagina; 1 = resting position; 2 = straining position.
If the intraabdominal pressure equalization theory were to be correct, a midurethral cough transmission ratio of 91% such as was registered in FIG 1 would be an impossibility, as virtually the whole urethra is situated below the pubic bone.

pressure rise preceded the bladder pressure rise. No correlation was found between the position of the bladder neck relative to the inferior border of pubic symphysis, and urinary incontinence, (16). The principal reason why the pressure equalization theory still seems to have currency, is that patients with stress incontinence are frequently cured by bladder neck elevation surgery. However, bladder neck elevation is not a pre-requisite for cure of SI. Vaginal repair (17), which does not elevate the bladder neck, may cure SI in more than 50% of cases. Cure of SI (without bladder neck elevation) has been demonstrated by correction of the 6 specific anatomical defects (1), (p53-79). Included in this group were many patients whose bladder neck remained below the inferior border of pubic symphysis (1), (p57) after cure.

Historical basis for the theory of detrusor instability. The entity presently called "detrusor instability", ICS (18) is not new. It has existed in one form or other at least since 1905, being variously called 'active incontinence', 'uninhibited 'or 'hypertonic' bladder. 'unstable bladder', Bates (19). An indirect reference to this was made already in 1887 by Guyon (20) "Cystite Douloureuse".

The early physiologists related the sensations of bladder filling to the afferent nerves running from the bladder to the spinal cord and the efferent nerves running from the spinal cord to the bladder, Barrington (21), Fernsides (22). Fernsides described complete and incomplete interferences with the power of holding urine both on the effector side and on the afferent side. Included in these were local interference. It was a simple matter, then, to impute the occurrence of bladder instability to abnormalities in this circuit. During cystometric studies carried out by Rose (23) and Parker and Rose (24), characteristic patterns were observed, similar to those found with neurological lesions. Included in this category were patients with senility or "insufficient cerebrum" on the efferent side and unspecified "local" lesions on the afferent side.

Denny-Brown (25) observed the detrusor's tendency to spontaneous all or none contraction "the process of storage of urine and its evacuation occurs therefore in a reservoir of which the distension excites a tendency to an automatic discharge".

Denny-Brown in 1933 measured urethral and bladder pressures simultaneously. He demonstrated that in the normal patient the involuntary micturition initiated by bladder filling could be controlled voluntarily. Most authors, however, were unwilling to allow possibility of any direct voluntary control over smooth muscle though some authors in particular, Rehfisch (26) Adler (27) & Le Gros Clarke (28) believed that voluntary control was possible. Muller (29) suggested that the afferent impulse arose in the voluntary external sphincter so that any effort to micturate would affect the bladder indirectly.

Denny-Brown agreed that a proprioceptive afferent stimulus for the reflex e.g. arising from the muscles themselves was difficult to exclude. Voluntary suppression of the vesical activity was "absolute and unequivocal". A reciprocal relationship was noted between urethral relaxation and detrusor contraction, i.e. the internal sphincter relaxed when the bladder contracted.

Lapides (30) also described the "uninhibited neurogenic bladder" in a group of patients who had no evidence of neurological disturbance with symptoms of urgency, frequency and precipitate micturition. He attributed such disturbances to incomplete development of cerebral integration much as occurs in a young child. It was described as dyssynergic detrusor dysfunction, Hodgkinson (31) psychogenic bladder, Youssef (32), an uninhibited bladder by Ingelman-Sundberg (33).

In more than 1000 combined cine/pressure/flow studies, Bates et al (19), it was objectively demonstrated that many patients who lost urine on coughing also initiated a detrusor contraction, and that coughing could stimulate detrusor contraction per se. Of patients with recurrent symptoms of incontinence after surgery, more than 2/3 were found to have unstable bladders. An unspecified number of patients with preoperatively unstable bladders showed no improvement in symptoms after repair operation. Bates (19) claimed that the distinction between stress and urge incontinence may be difficult or impossible on the symptoms and examination alone, i.e. the history of leakage on rising from a chair or walking may be particularly difficult to interpret when not associated with urgency. The purpose therefore of objective studies was to isolate that group of patients unlikely to respond to surgery who had bladder instability. This viewpoint has been reinforced by most investigators (34-39). Not all studies indicate low surgical success rate with pre-existing detrusor instability. A high success rate was demonstrated with incontinence surgery in patients with pre-existing detrusor instability (40,41).

Thus most investigators unequivocally accepted that bladder instability as diagnosed urodynamically was the prime pathogenic disturbance with symptoms correlating at best, less than 50%, (42-47).

The diagnostic process of filling cystometry was not without its critics, however. Some (48) counselled caution because at best urodynamics created an artificial situation because of the fast fill process.

The concept of bladder instability was further refined by the various committees of the International Continence Society 1976 (49) The term "detrusor instability" was introduced to describe a detrusor which was objectively demonstrated to contract spontaneously in a phasic pattern on provocation during the filling phase while the patient was attempting to inhibit micturition.

There are many problems associated with assessment of a patient (50), a principal one being that symptoms mean different things to different people, with wide individual variation. Urodynamics offered hope for the future as it was a scientific physiological method which was analytical and therefore could overcome the "label system" inherent in a symptomatic approach (50). In particular biology needed mathematical rationalization to become a true science (50). In summary, the concept of "detrusor instability" has evolved into a clinical entity, endowed with mathematical precision. It is commonplace for all symptoms and signs relevant to bladder instability to be compared against the gold standard of "detrusor instability", and to be invalidated if there is a conflict with this standard. "Detrusor instability" has, however, never been formally tested as a theory.

According to (1) however, urge symptoms, "urethral instability", "detrusor instability", and actual urine loss may all be mainly different manifestations of a prematurely activated micturition reflex. Using a urethrocystometric technique (51), 78% of 115 patients with a prior history of urge incontinence presenting with a full bladder and subjected to a handwashing test, were noted to experience one or both of the following: fall in urethral pressure, and followed some seconds later by a rise in detrusor pressure, exactly as occurs in normal micturition

(52) (53). It was also recently demonstrated (54) by direct observation in 77 patients who lost urine with a hand-washing provocation test, that if the patient reported urge symptoms in association with urine loss, the patient's testimony (history of urge incontinence) was likely to be more than 95% reliable. Using other manifestations of the micturition reflex, such as urine loss, or urge symptoms as the gold standard, it was concluded that the urodynamic process itself appeared to be defective, not the symptomatology. The reason may lie in what cystometry is attempting to measure, an end point of a complex chaotically determined biological process.

The chaotic nature of biological systems.

"The entire scientific enterprise represents a search for algorithmic compressions of data (55). These are often represented by theories or laws". In a physical system, they can be determined mathematically.

Natural systems (this would include such terms as detrusor instability), however, cannot be algorithmically compressed (55), and tend to be chaotic, and therefore not given to linear mathematical derivation (56). Some familiar examples include turbulent fluids, fibrillating hearts, dripping taps etc.

Urine retention or loss by the bladder is a complex process. Barrington (21) described 5 reflexes concerned with the initiation of micturition alone. Since then a plethora of initiatory and inhibitory centres have been demonstrated in the cerebral cortex, pons, medulla, cerebellum, midbrain, basal ganglia and hypothalamus, Fenely (57). Added to this must be the impact of the urethral, bladder neck and voluntary closure mechanism (1), with all their component individual reflexes, the impact again on these by the 6 anatomical defects (appendix A) the effect of multiple hormones, patients' moods and psychological and even mental states (58) etc. *According to the Chaos Theory, each of the factors described, no matter how small, has the capacity to make an impact on the process of urine retention/expulsion, and therefore, depending on the interaction of each and every component factor with another, actually change the end result.* This explains how, for example in pad testing, there is poor repeatability of results in the individual patient, but, a better correlation within the group. This can be attributed to the greater number of symptoms assessed (76a). Similarly, taking the premature activation of the micturition reflex as being the ultimate cause of both urge symptoms and "detrusor instability"(54), the diagnostic efficiency of urge symptoms is necessarily much higher than a one-off reading on a machine, given that the latter is being compared with the collective memory of the patient (76a).

In summary then, the chaotic nature of the urinary control system would appear to preclude precise mathematical assessment by a linear system such as cystometric testing (76a). Also, if, as appears to be so, involuntary urine loss caused by detrusor contraction may be mainly a premature activation of the micturition reflex, then the necessity for cystometric testing for detrusor instability, must also be questioned (76a), especially as the patient's history of urge incontinence is likely to be accurate (54).

The present status of the pressure equalization and "detrusor instability" theories.

"Scientific theories are universal statements"(59). Using such universal laws, it is possible to give a causal explanation, and predict singular events. Ideally a theory should be simply expressed, consistent and falsifiable. Though it is a self obvious assertion that a theory which contains an internal contradiction is invalid, nevertheless, we frequently work with statements, which, though actually false, nevertheless yield results which are adequate for certain purposes", Popper (59). Popper proposes two rules of methodology:

1. Scientific statements can never reach a point where they can be regarded as finally verified.
2. Once a hypothesis has been proven to some degree of validity it should not be allowed to drop out without good reason i.e. unless it can be replaced by another hypothesis which is "better testable" or the falsification of one of the consequences of the hypothesis.

The two theories on which much of the present science of urogynaecology has been based, the pres-

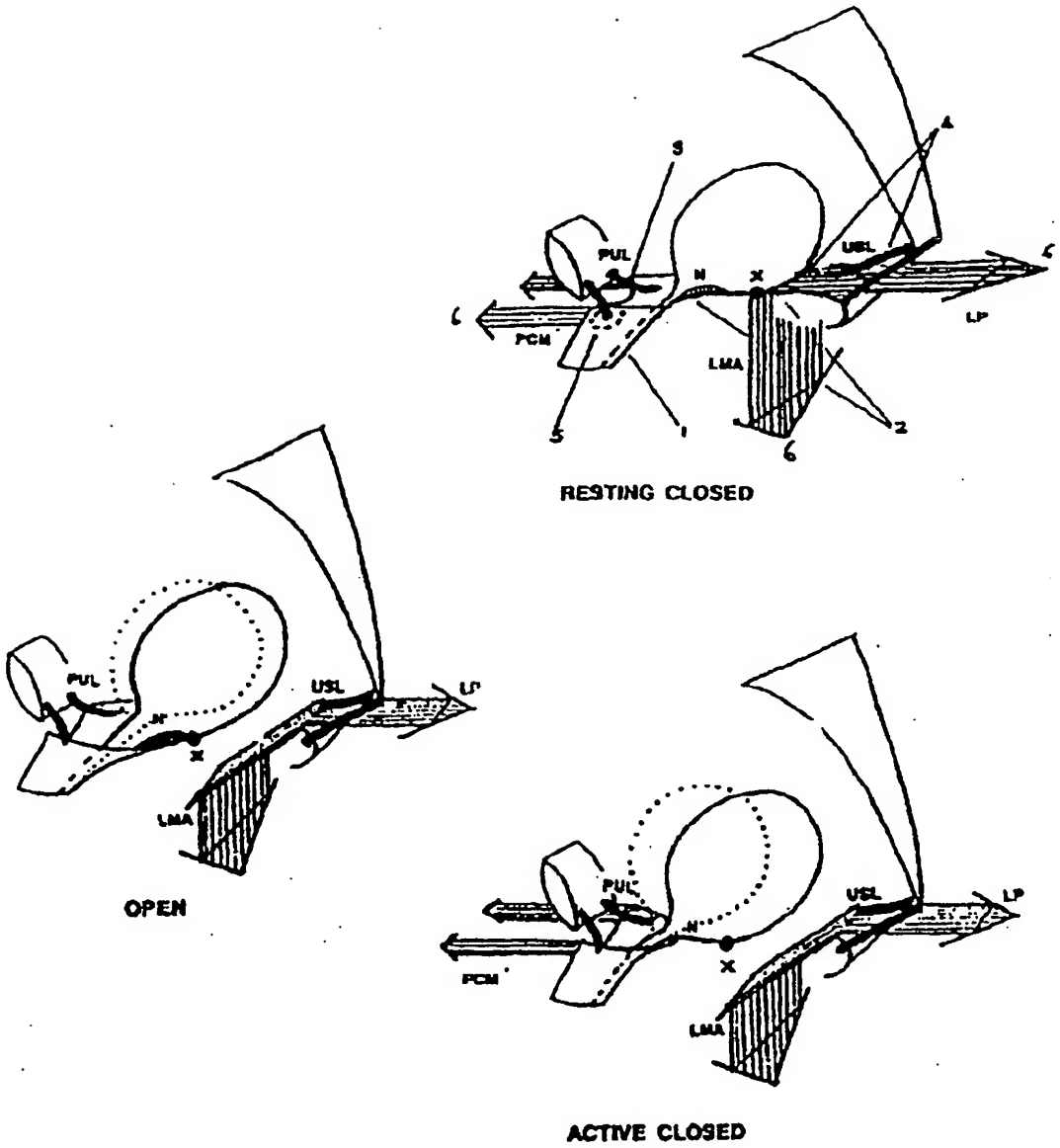


FIG 2

Mechanisms of opening and closure the urethra/bladder neck.

This represents a sagittal section of the bladder and urethra nestled in the anterior vaginal wall. PUL = pubourethral ligament; USL = uterosacral ligament; PCM = anterior portion of the pubococcygeus muscle, LP = levator plate LMA = longitudinal muscle of the anus. The numbers signify the position at which the various anatomical defects occur, according to the classification. 1: suburethral vagina. 2: supralevator vagina. 3: pubourethral ligament. 4: uterosacral ligament. 5: collagenous insertion of the pubococcygeus muscle. 6: striated muscle damage

In the functional sense, striated muscle requires a fixed insertion into the vagina/ligaments for efficient contraction. Laxity in the system may result in deficient closure forces being generated, so that the bladder neck remains in the "open" position .

sure equalization theory (14), and the concept of "detrusor instability" (18) will be examined in the above context. As concerns the pressure equalization theory, (14), operative elevation of the bladder neck has been demonstrated to efficiently cure stress incontinence, so that many surgeons recommend such a procedure as the operation of choice (60). As concerns the detrusor instability theory, it has been demonstrated that bladder neck elevation surgery is associated with a high failure rate (19) (35) (36), so that urodynamic testing for this condition is regarded as essential for the diagnosis to be made, allowing alternative forms of treatment. Thus both the theories as described have validity, in that they are being effectively used as working hypotheses. *It follows that it is not sufficient to simply present evidence to invalidate an existing theory, eg FIG1. Ultimately, any challenge to the theory of "detrusor instability" (e.g. by the Integral Theory (1), has to meet the dual requirements of not only invalidating the existing theories, but also, to be able to "better explain" all the various phenomena associated with urinary incontinence.*

The new Integral Theory is presented with the specific perspective of attempting to "better explain" as many observations as possible on urinary incontinence with respect to the theory as stated below.

The Integral Theory of Female Urinary Incontinence

states that: *stress symptoms, urge symptoms, and symptoms of defective flow may all derive, for different reasons, from laxity in the vagina or its supporting ligaments, a result of altered connective tissue.*

In the following, the Integral Theory will be penetrated from different aspects, starting with morphologic and physiologic considerations.

ANATOMY AND PHYSIOLOGY

Involuntary urethral and bladder neck closure mechanisms.

These are separate, but linked by an elastic bridge, the "zone of critical elasticity"

The voluntary closure mechanism or "cutting-off" mechanism uses a different group of muscles which elevate the bladder neck. All 3 mechanisms are simultaneously demonstrated in FIG 6.

ROLE OF VAGINA IN BLADDER NECK OPENING AND CLOSURE.

The tensioned vagina regulates opening and closure of the bladder neck.

"Resting closed position". The numbers 1-6, FIG 2 signify the position at which the various anatomical defects occur. The vagina is suspended anteriorly by the pubourethral ligament (PUL) (10), superiorly by the arcus tendinaeus fasciae pelvis, (61), and posteriorly by the uterosacral ligament (USL) (1). The vagina is tensioned like the membrane of a drum against its suspensory ligaments, by slow twitch muscle contractions of pubococcygeus muscle (PCM) anteriorly, levator plate (LP) posteriorly, and the longitudinal muscle of the anus (LMA) inferiorly. At the same time, the stretched vagina 'supports' the nerve endings (N) at the bladder base preventing premature activation of the micturition reflex, or "bladder instability"*.

* "bladder instability" is not actually defined by the ICS (18), but by convention it consists of an involuntary loss of urine in association with a detrusor contraction.

"Active closed". Fast twitch contraction forward of (PCM) pulls the two ends of the ascending vagina (FIG 2) tightly around the urethra, closing it off and immobilizing it while (LP) and (LMA) pull the bladder down and back like an elastic balloon, kinking off and closing off the urethra like a hose. For these opposite muscle movements to occur there needs to be sufficient elasticity in the bladder neck area, zee, FIG 3.

"Open position". As part of the micturition reflex, (PCM) relaxes. This allows (LP) and (LMA) to uninhibitedly pull at (X), opening the bladder base, creating a "funnel", enlarging the urethral outlet (1) (P21). At the same time, this stretching stimulates the nerve endings (N), activating and reinforcing the micturition reflex, which is further re-enforced by the presence of urine in the proximal urethra (21)

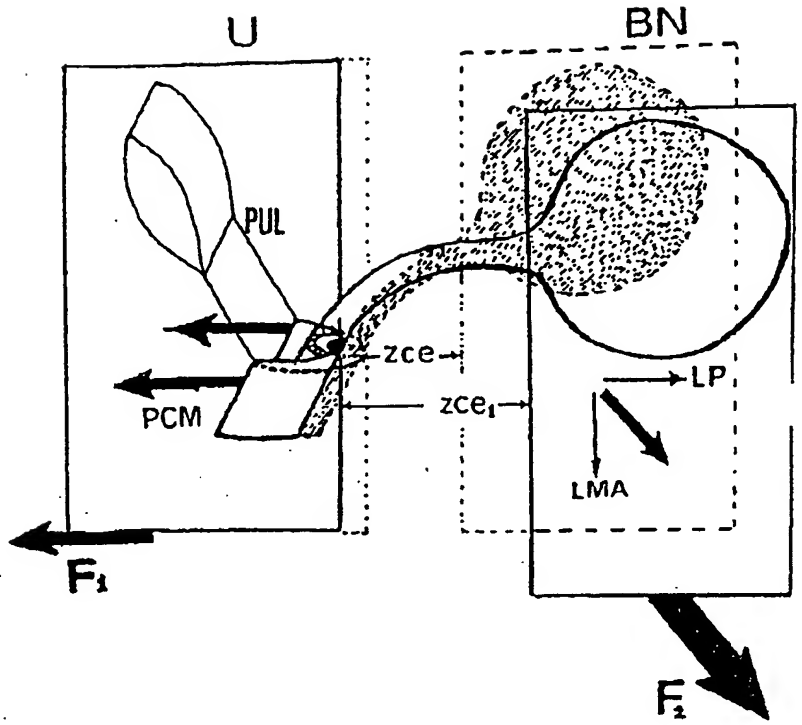


FIG 3
Urethral and bladder neck closure mechanisms.
U = urethral closure mechanism; BN= bladder neck closure mechanism; zce = zone of critical elasticity; zce1 = zone of critical elasticity during straining/micturition; F1= anterior force PCM = pubococcygeus muscle; F2 = postero-inferior force; LP =levator plate; LMA = longitudinal muscle of the anus. *The urethral (U) and bladder neck (BN) closure mechanisms, FIG 3, are separate and require adequate elasticity in the intervening tissues to operate efficiently.*

In a functional sense, such elasticity must be present in zce, the "zone of critical elasticity". This zone acts "like an accordion", permitting "U" and "BN" to perform their closure functions independently. There are two independent and opposite forces acting on the vagina, F1 and F2. F1 acts in the front part of vagina, and closes the urethra; F2 acts in the posterior part of vagina and closes the bladder neck. It opens bladder neck when F1 relaxes. During opening and closure, zce elongates to zce 1. F1 is the weaker force and is created by forward movement of the pubococcygeus muscle. F2 is the stronger force, and is created by the vectors of levator plate (LP), and longitudinal muscle of the anus (LMA). If zce is too tight, F2 opposes F1, so that the bladder neck now opens on being given the signal to close.*

* strictly speaking, the " zone of critical elasticity extends from the insertion of the pubo-urethral ligament to the vesico-vaginal ligament (1) (p8).

RADIOLOGICAL PROOF OF THE OPENING AND CLOSURE MECHANISMS,
as suggested in FIGS 2 & 3.

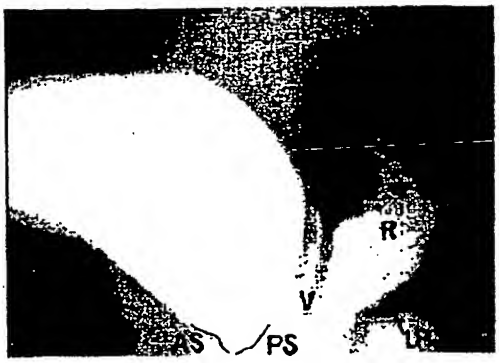


Fig 4a.
Resting closed position
R = rectum; V = vagina; LP = levator plate, with arrow pointing to its superior border; AS = anterior bladder shelf; PS = posterior bladder shelf.
This is a videocystourethrography of a 50 year old continent woman in the resting position. The bladder neck is situated well below the horizontal line which intersects the ano-rectal junction. The levator plate (arrow) lies almost parallel to the floor. The anterior bladder shelf AS (9), at the bladder base is well defined. The posterior bladder shelf PS (9), is visible as the posterior wall of bladder angulates forwards to join the urethra.

FIG 4b.
On straining
The anterior shelf does not alter, consistent with a tensioning effect (1) (p21), by the pubovesical ligament. The bladder base has been pulled downwards, and the posterior shelf flattened. The vagina, rectum, anorectal junction, and anterior part of levator plate (arrow) have been synchronously pulled downwards, consistent with a neuromuscular co-ordinated reflex (1) (p21).

FIG 4c
EMG and urodynamic correlations
U = urethral pressure; B = bladder pressure; s = straining; c = 'cut-off'

The bladder pressures recorded during straining, FIG 4b and "cutting-off", FIG 4c, were equivalent.

Note that the levator plate and pelvic organs are elevated during "cutting-off" (FIG 4c), but depressed during straining (FIG 4b). This makes the commonly held viewpoint that intra-abdominal pressure causes downward displacement of the pelvic organs unsustainable.

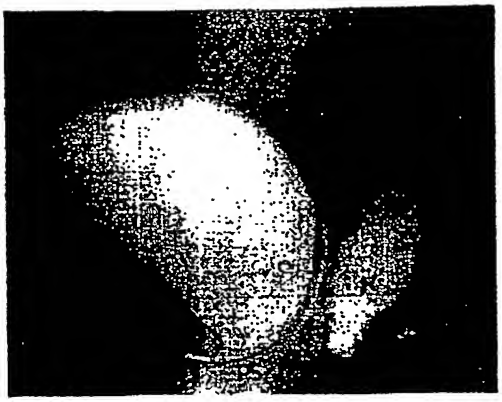


FIG 4d
At micturition
All the structures are in virtually identical positions as in straining (FIG 4b) as predicted (1): the almost identical descent and angulation of the superior border of the levator plate (arrow); descent of anorectal junction, bladder base, and vagina, (1) (p19). The anterior bladder shelf (AS) appears to be anchored, and of the same shape as in FIG 4b: "during bladder neck opening, exactly the same events take place as in bladder neck closure, except that the anterior portion of pubococcygeus muscle reflexly relaxes, enabling the levator plate to open proximal urethra, and to stimulate the nerve endings at bladder base, initiating the micturition reflex; (1) (p11)" and, "the active opening of bladder neck into a funnel by traction of the pelvic floor muscles on the vagina is an essential element for the expulsion of urine." (1) (p21).

FIG 4c
Voluntary closure mechanism ("cutting-off")
At "cutting off" in mid-stream (1) (p10), an acute angle returns to the posterior shelf of bladder base, the ano-rectal junction and superior border of levator ani muscle (arrow) are elevated well above the horizontal line. The vagina and bladder neck appear to have been lifted upwards and forwards, clearly different movements from straining (FIG 4b). Pressure generation is, however, equivalent (FIG 4c).

FIG5
Postero/inferior stretching of vagina during urination
A standing lateral x-ray of an asymptomatic patient in the "resting closed" position is superimposed on a micturition film. Three vascular clips have been applied to the vagina, from below upwards to: midurethral area, bladder neck area, and 3-4 cm posterior to the bladder neck area. Dotted lines indicate the position of the anterior vaginal wall. R = rectum in the resting position, and R1 in the straining position. The black line joins the inferior border of pubic symphysis to the lower end of the coccyx.
The upper clip, 3-4 cm posterior to the bladder neck (equivalent to point "X" in FIG 2), is stretched backwards. The vagina in the area of urethra and bladder neck is stretched backwards and downwards, synchronously with the rectum. The angulated shape of the anterior wall of vagina has been flattened out, ("funnelling"). That segment of vagina between the lower and upper clip corresponds approximately to "zce" (FIG3) in the resting position and "zoc1" in the position of micturition.

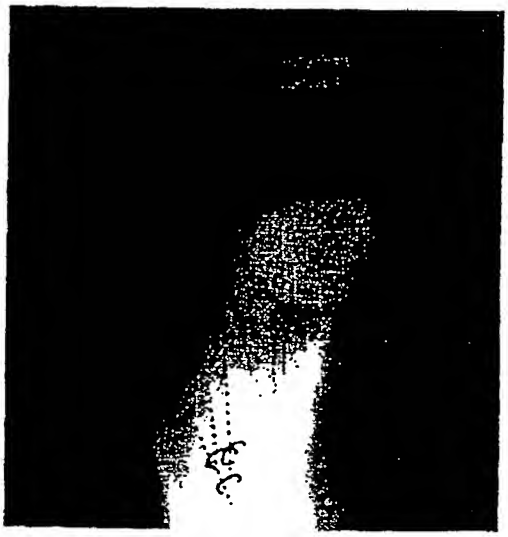


FIG 6
Differential stretching of vagina during straining and "cutting-off", FIG 6.
This figure represents three superimposed standing lateral x-rays of a normal patient. The vagina, dotted lines, is shown in the "cut=off" (C), "resting closed" (R), and straining (S) positions. Vascular clips have been applied to the vagina in the midurethral and bladder neck areas. Radio-opaque dye delineates the Foley catheter balloon. During "cut-off" (C), the vagina and bladder neck are simply lifted upwards and forwards of the resting closed position (R). During "straining" (S), the upper part of vagina appears to have been stretched longitudinally backwards, and pulled downwards in the bladder neck section, (upper clip). The midurethral area of vagina, however (lower clip), is pulled downwards and forwards. The tube of the Foley catheter has also been pulled forwards in this area.

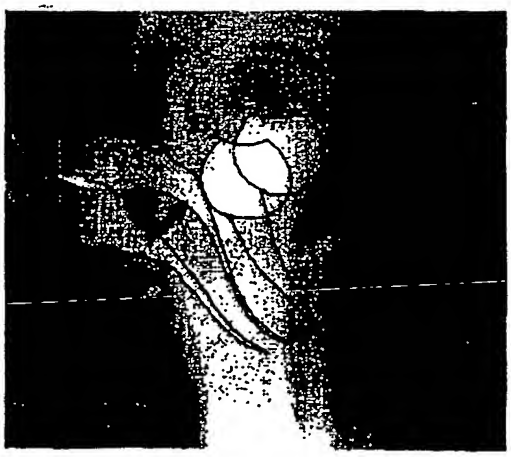


FIG 7a

High elasticity in vagina and PUL.

This figure represents two superimposed standing lateral x-rays of a young normal patient; ; B = Foley balloon positioned in bladder, V = vagina wall; 1 = resting closed position; 2 = active closed position (straining); arrows indicate the transverse sulcus of vagina in the bladder neck area. A = the presumed position of the pubo-urethral ligament's insertion into vagina.

The whole vagina moves backwards and is angulated downwards, as is A, indicating significant elasticity in the PUL. Fulcrum point "A" is situated well below the transverse sulcus of vagina, (arrows). and therefore, bladder neck. This indicates that the correct tethering point of urethra during involuntary closure is well below the bladder neck. Surgical restoration should likewise be in this position. Comparison with FIG 5 (micturition) graphically indicates the anatomical reason why urinary retention almost invariably occurs post-operatively in patients following surgical elevation of the bladder neck. The middle and upper clips in FIG5 would be prevented from "funnelling". "Visco-elastic creep" over the ensuing days/weeks rescues the situation. This gradually loosens the tissues in the bladder neck area, permitting muscular opening of the outflow channel, as in FIG 5.

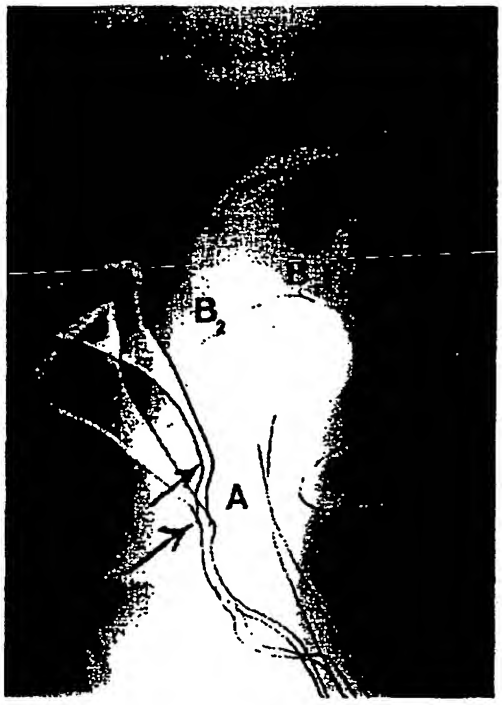


FIG 7b

Inelasticity of vagina and the pubourethral ligament.

This figure represents two superimposed standing lateral x-rays of a 60 year old patient with stress and urge incontinence ; B = Foley balloon positioned in bladder, V = vagina wall; 1 = resting closed position; 2 = active closed position (straining); arrows indicate the transverse sulcus of vagina in the bladder neck area. A = the presumed position of the pubo-urethral ligament's insertion into vagina. *There is very little extension downwards at point A , bladder neck and vagina, indicating poor tissue elasticity. The transverse sulcus (arrows) is very close to point A, indicating minimal posterior extension of PUL. Therefore the margin between urethral fixation and over extension of vaginal tissue in the bladder neck area (zce) would be very small indeed. Such a patient is at risk of developing the "tethered vagina syndrome" with a bladder neck elevation procedure (1),. as there is not the same possibility as in FIG 7a for restoration of elasticity through "visco elastic creep"(cf part II).*

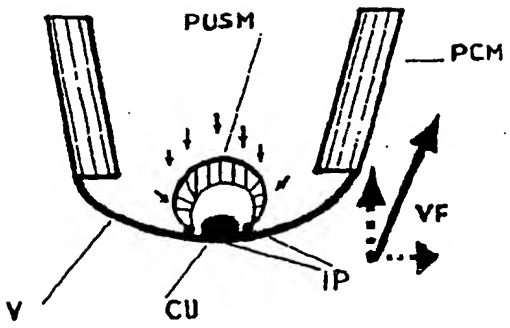


FIG 8
Urethral closure mechanism.
This figure represents a cross-section taken through the midurethra. V = vagina; I P = insertion points of PUSM; CU = cresta urethralis; arrows = vector forces.

CLOSURE MECHANISMS.

Urethral Closure Mechanisms

Contraction of the anterior pubococcygeus muscle (PCM) closes the urethra. Contraction of the periurethral striated muscle (PUSM) provides a water-tight seal in the presence of a trophic mucosa.

Anatomically, the urethra lies suspended in a "hammock"(1), (62), (63), (64) of vaginal epithelium as indicated in FIGS 8, 17. Contraction of the anterior portion of pubococcygeus muscle (PCM), FIG 8, pulls the cresta urethralis (CU) towards the periurethral striated muscle (PUSM) by tensioning the vagina (V), at the same time anchoring the insertion (IP) of the periurethral striated muscle (PUSM).

Most of the work for closure is performed by the anterior portion of the pubococcygeus (PCM). The PUSM merely creates a water-tight seal by its action on trophic urethral mucosa. The slow twitch fibres of the (PUSM) contribute to resting urethral pressure. The (PUSM), at least in a functional sense, appears to have a fast-twitch action, as noted by needle EMG studies (62). Our data indicates (1) (33-35), FIG 10, that it is mainly this fast twitch contraction of the (PUSM) which is recorded by the pressure transducers during the cough transmission ratio (CTR) determinations. Defects 1-3, FIG 2 may affect the urethral mechanism and cause incontinence of urine. The urethral closure mechanism may maintain closure even in the presence of an incompetent bladder neck. Entry of urine into the proximal urethra has been observed on VCU without accompanying incontinence (65).

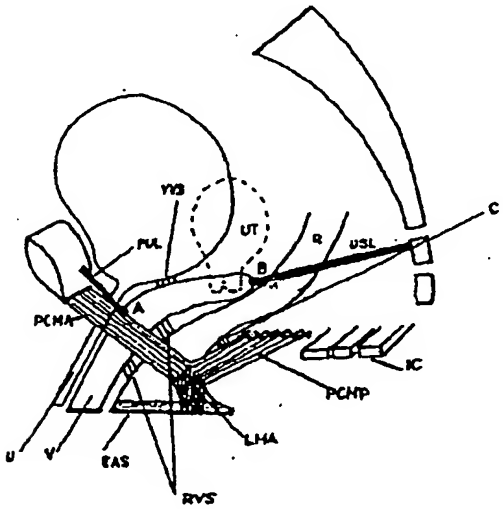


FIG 9
Bladder neck closure mechanism
PCMA = anterior portion of the pubococcygeus muscle; PUL = pubourethral ligament; PCMP = posterior portion of pubococcygeus muscle; IC = ilio/ischio - coccygeus muscle C = connective tissue joining the levator plate to the posterior wall of rectum, R; V = the vagina; RVS = rectovaginal septum; VVS = vesicovaginal septum; LMA = longitudinal muscle of the anus; EAS = external anal sphincter; USL = uterosacral ligament; UT = uterus; U = urethra; A = insertion point of PUL; B = insertion point of USL.
The essential principle of this mechanism is that the horizontal striated muscles of the pelvic floor contract, so becoming semi-rigid. These are then pulled downwards in their mid-section by contraction of the longitudinal muscle of the anus (LMA).

Bladder Neck Closure Mechanisms

This downward action indirectly pulls down the bladder base, "kinking" it like a hose at the internal orifice of the immobilized urethra. The urethra is immobilized by forward contraction of the anterior portion of the pubococcygeus muscle, PCM (A). This pulls against the pubourethral ligament (PUL), which acts as a fulcrum. The levator plate comprises the posterior portion of pubococcygeus muscle (PCMP) and ilio/

ischio-coccygeus muscle (IC). It contracts and pulls the bladder base backwards against the (PUL) by pulling on rectum and vagina. This movement requires a coordinated involuntary tensioning of the fibromuscular septa and the smooth muscle of the organs themselves (1), (p21), so that they all move in concert, FIG 12b. The now semi-rigid levator plate is tilted downwards, like a trapdoor, FIG 4b, by the longitudinal muscle of the anus (LMA).

The LMA extends from the level of the levator fascia above to the perianal skin below. It draws fibres from the pubococcygeus, pubo-rectalis, and ilio-coccygeus muscles, (66), surrounds the rectum, and is inserted into the external anal sphincter (EAS), (67). Posterolaterally there exists a circum-anal space (66) which separates this muscle from the rectum. This presumably allows the LMA to pull down the levator plate without in any way compromising the rectal wall. The EAS must be pre-tensioned for efficient functioning of this mechanism. Relaxation or immobilization of PCM (A) for whatever reason, will push the system into the "bladder neck open" mode, creating a funnel, FIG 5. At the same time, intact cardinal ligaments, uterosacral ligaments, and rectovaginal septum are necessary for transmission of the (LMA) contraction to rectum, vagina and bladder. Defects 2-6, FIG 2 may affect the bladder neck closure mechanism and cause incontinence of urine.

Voluntary Closure Mechanisms.

Whereas the urethral and bladder neck closure mechanisms are interdependent and involuntary, the voluntary closure mechanism, FIGS 6 & 4e, can be radiologically and ultrasonically demonstrated to be quite different and under voluntary control. It results in elevation of the bladder base, rather than descent, and is thought to be mediated either by the lateral group of pubococcygeus muscles, or by the puborectalis, (1) (p10). In the normal patient, the desire to micturate is also controlled by the voluntary closure mechanism, which may counteract the stretching of nerve endings at bladder base by voluntary elevation of the pelvic floor, (1) (p10,29), FIG 4e. This mechanism also has the capacity to inhibit or reverse the micturition reflex, "VC" FIG 13.

PATHOPHYSIOLOGY

Anatomical classification of female urinary incontinence according to laxity.

The number preceding the defect corresponds to the number in FIG2. Specific clinical symptoms associated with each particular defect are summarized in Appendix A. Depending on the site of the laxity, and the "sensitivity" of the nerve endings, the patient could experience stress incontinence, urge incontinence, defective bladder neck opening*, or various combinations of all three.

(1) Suburethral vaginal ("hammock") defect.
(2) Excessive tightness/scarring in the bladder neck zone.
(3) Loose pubourethral ligaments.
(4) Loose uterosacral ligaments/lax supralevator vagina.
(5) Damaged collagenous insertion of pubococcygeus muscle into vagina.
(6) Striated muscle damage
    a) Trauma to external anal sphincter
    b) Levator plate - torn muscle insertion to pubic bone.
    - lax collagenous insertions.
    - paralysis.

* Given the common aetiology, defective opening should be considered as part of the same spectrum of urinary dysfunction.

In the context of this anatomical classification, the present ICS (18) classifications of "detrusor instability", "urethral instability", "genuine stress incontinence" etc. are considered to describe observed events.

How symptoms relate to the classification.

In general, defects in the front part of the vagina are more likely to be responsible for SI, while defects in the back part of the vagina are more likely to be responsible for symptoms of defective opening, Appendix A. Symptoms of frequency, urgency, and nocturia may occur equivalently with either. Diagnosing anatomical defects 1-6 in a particular patient does not mean that she will necessarily have symptoms of incontinence. Other factors are also impor-

tant, such as the urethral pressure, which has vascular and smooth muscle components, and the ability of the various compensatory mechanisms, in particular the involuntary, and voluntary mechanisms, FIGS 4-6. The latter may be learnt, and include elevation of the pelvic floor by voluntary contraction, (pelvic floor exercise), and the inhibitory mechanisms of the brain (bladder training exercises).

Defect 1- Suburethral vaginal defect - excessive looseness.

The symptom of "dampness throughout the day" is often due to a defective urethral closure mechanism.

Pathogenesis and clinical diagnosis There is observable laxity in the suburethral vaginal mucosa. Loss of urine in the supine position on coughing may be controlled by the "pinch test" (1) (p33-35), i.e. taking a small fold of vagina paraurethrally with Littlewood's forceps, and asking the patient to cough. Urine loss controlled by this test demonstrates the importance of an adequately tight suburethral vagina for urethral closure. Many patients were able to pass urine during this "pinching"(1) pp 33-35), indicating that the mechanism as described in FIG 8 was the operative mechanism, not urethral obstruction. In the presence of an intact PUL, there may be a low transmission ratio (CTR). If the pubourethral ligament fulcrum point, PUL, FIG 2, is intact, PCM pulls against it as it would in the normal patient. Therefore any laxity in the suburethral vagina means that the insertion points IP, FIG 8, cannot be anchored. The (PUSM) cannot contract efficiently, resulting in deficient urethral closure, and low cough transmission ratio (CTR). If the PUL fulcrum point is lax, then PCM and LP can no longer contract independently against it, and therefore LP may overpower PCM due to the fact that the vagina stretches first in the longitudinal axis, FIGS 17, 17a. The result is that the insertion points, IP, are tensioned, PUSM now contracts efficiently, and so the CTR may register 100%, even though there is no urethral closure. This is explained further in the biomechanics section.

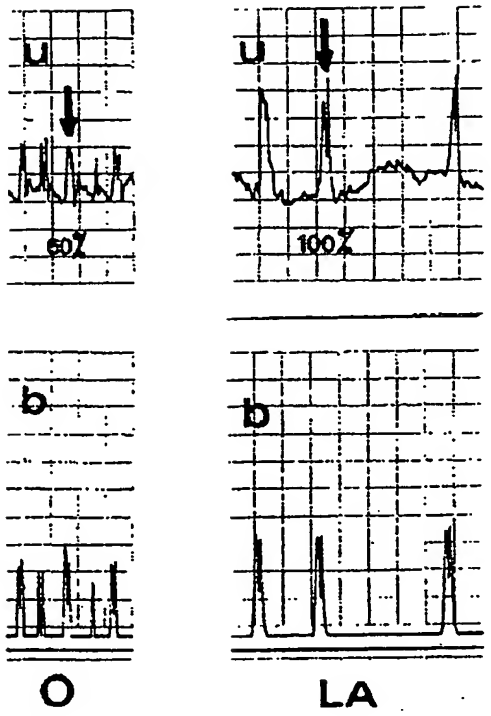


FIG 10

Effect of periurethral oedema on cough transmission ratio.

u= urethral pressure; b = bladder pressure; O = pre-injection readings; LA = pressure readings after para and suburethral injection of a diluted local anaesthetic solution.

This is a urethrocystometric tracing taken from a patient with SI. As seen in the figure, CTR increased from 60% to 100% after paraurethral local anaesthetic injection. According to what is said above, this may be explained by the oedema immobilizing the insertion points IP of the (PUSM)(1). The results are consistent with the concept of restoring efficient contraction, and increased urethral pressure derived from the periurethral striated muscle.

The symptom of "dampness throughout the day" is often due to a defective urethral closure mechanism as described above, often combined with a defective mucosal seal due to an atrophic urethral mucosa and deficient vascularity causing a low maximal urethral pressure. Improvement in symptoms with oestrogen therapy can be attributed to improvement in the mucosal seal. Often such leakage can be improved by inserting a vaginal tampon. Low urethral pressure and low vaginal elasticity is diagnosed by the "slow leak speculum sign" (1) (p66): as the examining

Sim's speculum is pushed gently but firmly into the posterior fornix of vagina, a slow steady leakage of urine is observed, relieved by taking out the speculum. Often the leakage begins even as the speculum enters the vagina. Indeed, in extreme cases, such urine loss may even be elicited by simply stretching the suburethral vaginal mucosa. Most likely, this phenomenon is due to low urethral pressure associated with deficiency or hampering of the forward urethral closure force, F1, FIG 3.

Defect 2 - Excessive tightness/scarring in the bladder neck zone:

We have described this as the "tethered vagina syndrome" (1) (p63).

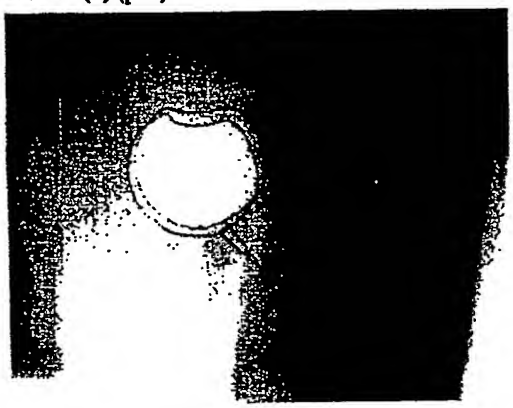


FIG 11a

Tethered vagina syndrome - preoperative.

A preoperative straining x-ray has been superimposed on a resting radiograph in a patient with urinary incontinence due to the "tethered vagina syndrome" in the presence of a net deficit of tissue elasticity in the anterior vaginal wall. There is virtually no movement on straining. This condition is invariably iatrogenic.

Scarring or loss of elasticity in the "zone of critical elasticity" (zce), of the vagina due to previous vaginal repair or bladder neck elevation surgery , may "tether" the pubococcygeus muscle (PCM) to the levator plate (LP), FIG 3. The zce in effect, acts as an inelastic connecting rod, so that F2 overpowers F1. The bladder neck opens when given the signal to close.

Pathogenesis and clinical diagnosis. The "tethered vagina syndrome" is often associated with a low urethral pressure (1) (p64). Almost invariably, the patient wets prior to arrival at the toilet in the morning. In the worst cases, wetting begins just on getting out of bed. "Cutting off" is impossible. There may be no significant stress incontinence (1) (p64). Many patients complain of leakage on bending over, but without any stress incontinence on coughing, a "paradoxical leakage", as the pressure generated on bending over is far lower than on coughing (1) (p65). ZCE, FIG 3, is inelastic. F2 represents the powerful contraction of pelvic floor needed to contain the intra-abdominal organs; F2 easily neutralises F1, and so the bladder neck opens instead of closing. On examination, the vagina is usually very tight in the region of the bladder neck. There is no "swing" of the urethrovesical junction (UVJ) on straining. Insertion of a ring pessary may worsen the incontinence. Grasping the vagina with Littlewood's forceps just behind the urethrovesical junction and pushing backwards may sometimes induce urine loss on coughing where this symptom did not previously exist. In patients with associated low urethral pressure, the "slow leak speculum sign" (1) (p66) is often found to be positive. All these tests are based on stretching residual elasticity out of zce, FIG 3, so that F1 is prevented from closing the urethra.

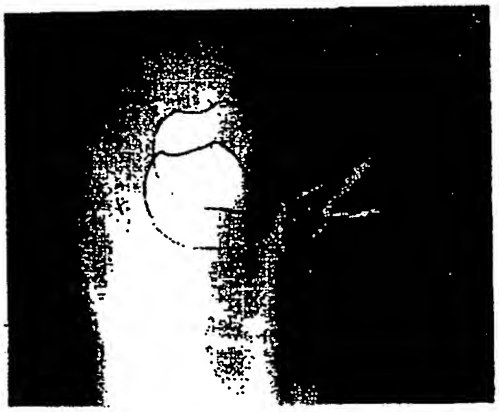


FIG 11b

Tethered vagina syndrome- postoperative.

The same patient as in FIG 11a following restoration of vaginal elasticity and cure by a free graft in the bladder neck area of vagina.

Surgical restoration of elasticity by I-plasty or free vaginal graft to the bladder neck area of anterior vaginal wall (1) (68) have, in our hands, frequently

induced normal excursion downwards of bladder neck during straining and restored continence (FIG 11b). Such surgical procedures as plastic surgery using full thickness grafts require uneventful healing. Rejection of the graft usually leads to further scarring and possible worsening of symptoms.

Forward tethering. If the bladder neck is too tightly anchored anteriorly to the pubic symphysis during bladder neck elevation or sling procedures, creation of a funnel (FIG5) by F2 may not be possible, leading to difficulty in bladder emptying and high postoperative residual urine. Some of these patients never urinate properly again.

Defect 3 - Pubourethral ligament defect.

This may be the most serious defect. The important fulcrum function is lost, so that both urethral and bladder neck closure mechanisms may be inactivated.

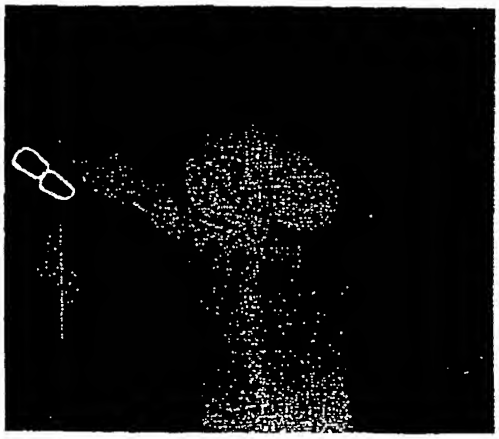


FIG 12a

Pubourethral ligament (PUL) defect - resting closed position.

This is a standing lateral x-ray of a patient with stress incontinence; PS = pubic symphysis; structures outlined with radio opaque dye: B = bladder; V = vagina; R = rectum; LP = levator plate.

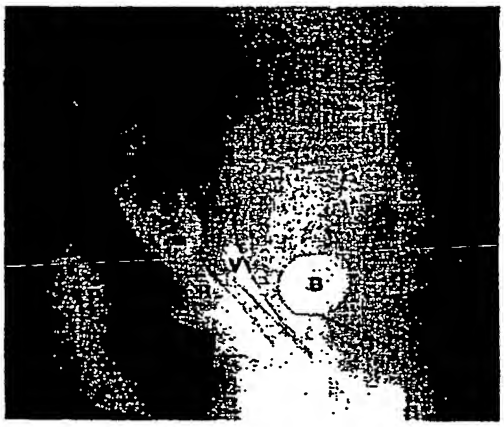


FIG 12b

Pubourethral ligament (PUL) defect - straining position.

Pathogenesis and clinical diagnosis. The bladder, vagina and rectum are all in the correct anatomical position at rest FIG 12a, but fall backwards on straining, FIG 12b, prolapsing synchronously below the inferior border of pubic symphysis. Active downward angulation of levator plate appears to have caused these events. Laxity of the pubourethral ligament (PUL) may be congenital, occur due to advanced age (collagen loss), or childbirth (1), p12). Such a defect may be suspected if the patient has difficulty in opening the last part of her bowels or if there is also some faecal soiling, (unpublished observations). Our Intravaginal Sling operation performed for urinary incontinence, cured, quite by accident, 30 patients with faecal incontinence. Also more than half of our patients with urinary incontinence who also complained of difficulty in "opening the last part of their bowels", were cured by this operation. Creation of an artificial pubourethral ligament (1), (p43-51) or collagenous re-insertion ("re-gluing") of vagina to the pubococcygeus muscle appeared to be the relevant factor in the cure of both symptoms.

In very old patients, there may be no urge or stress urinary symptoms as such, (1) (p53). The patients may present with "dropping their urine on the floor" on getting up from a chair. With a deficient PUL, there is no fulcrum for F1 to pull against, so that F2 overpowers F1, FIG 2. The bladder neck opens on being given the signal to close.

The IVS procedure cured 20/26 very old patients(mean age 81 years) with principally urinary urge incontinence (unpublished observations). Some of these patients presented simply with "dropping their urine on the floor" , and without symptoms of urine loss on coughing. In many of these patients, tightening of the suburethral vagina was not performed, indicating that deficiency of the pubourethral ligament/collagenous insertion of vagina to muscle was probably the prime defect.

Urethroscopically, on positioning the urethroscope just distal to the closed internal urethral meatus, opening occurs on asking the patient to strain (1) (p 11). A simple classical test for pubourethral defect is the Bonney test. Unilaterally applied, it is impossible to obstruct the urethra. The Bonney test works by anchoring the urethra, much in the same way as the pubourethral ligament does (1) (p34).

Defect 4 - Loose uterosacral ligaments/lax supralevator vagina:
This is due to laxity in the posterior fornix of vagina. The patient may have symptoms of urinary incontinence, defective emptying, pelvic pain, and high residual urine.
Pathogenesis and clinical diagnosis. It is likely that overdistension of the posterior fornix during labour, and transverse suturing of the vault without attention to its ligamentous supports during hysterectomy are important aetiological factors (1) (p71), though we have seen it less frequently as a congenital defect, becoming symptomatic after menarche. Laxity of the supralevator vagina may not allow adequate tensioning of the vagina below the bladder neck nerve endings. FIG 2, resulting in symptoms of frequency, urgency nocturia. F2 is diminished. Pressure transmission ratio at the Valsalva test may be positive instead of negative, as would normally be expected in a patient with urinary incontinence (cf also FIG 22 Biomechanics section).

The patient may have symptoms of defective emptying, pelvic pain, (cf Appendix A), findings of high residual urine, and varices noted laparoscopically at the site of the uterosacral ligaments (69). On examination there may be a bulge between the uterosacral ligaments, or presence of an early enterocoele. It is possible to perform a posterior fornix "pinch test" (1) (p34) by approximating the two lateral corners of the posterior vaginal fornix in the midline. Insertion of a ring pessary may similarly tighten the posterior fornix and bring a dramatic improvement in symptoms. As such it is a useful diagnostic test.

Defect 5 - Loose collagenous insertion between vagina and pubococcygeus muscle (1) (p58).
This is also a serious defect with symptoms similar to those found in a pubo-urethral ligament defect
Pathogenesis and clinical diagnosis. The vagina is inserted ("glued") to the undersurface of pubococcygeus muscle by collagenous connective tissue. An overstretched collagenous insertion point between pubococcygeus muscle and vagina, defect no. 5, FIG 2, may alter the bladder neck closure mechanism, as the muscle belly of PCM cannot properly be tensioned against the PUL fulcrum. It may also inactivate the urethral closure mechanism.

Defect 5 - may correspond to Bailey's type 2B defect (3) or "inferior support" defect (3), or to Richardson's paravaginal fascial defect (11) (12). Clinically, the presentation is similar to that for PUL defect. We diagnose it by inference* in patients whose bladder neck is radiologically in the correct anatomical position at rest and on straining, together with a loose suburethral vagina on clinical examination, in the presence of high cough transmission ratio. We have noted that many very old patients present for the first time with symptoms similar to those reported in the section on pubourethral defect, "dropping urine on the floor", faecal incontinence, etc. Radiologically, the bladder neck is in the correct anatomical position at rest and on straining. Differential diagnosis from (PUL) defect may not be easy if the bladder neck is situated below the inferior border of the pubic symphysis at rest.

* differentiation from a PUL defect is of academic interest only, as this anatomical defect is automatically restored by the Intravaginal Sling Operation,part IV, which "reglues" the vagina to the pubococcygeus muscle, (1) (p 58).

Defect 6 - Striated Muscle Damage.
A torn external anal sphincter is a rare, but correctible

defect. *Paralysis to the muscle floor is not considered to be a primary aetiological factor in female urinary incontinence, but rather, a qualitative contributory factor.*

Pathogenesis and clinical diagnosis. Swash in his unifying theory, attributes urinary and faecal incontinence to muscle paralysis (70). However, not all patients with pelvic floor paralysis were found to have urinary or faecal incontinence, and vice versa (70). The frequent finding of muscle paralysis in incontinent patients is explained according to (1), a connective tissue theory, as follows: the foetal head may damage the motor endplate of the pelvic floor, the vaginal connective tissue, or both. The pelvic floor muscles are an important support of urethra (10). Paralysis causes loss of muscle tone (71), so that a prolapsed position of bladder neck and other organs at rest may be caused by a partially paralysed pelvic floor. Many patients whose bladder neck lies below the inferior border of pubic symphysis have been cured by the intravaginal slingplasty procedure without bladder neck elevation (1) (p57). Accordingly we consider that muscle paralysis is not the prime cause of urinary incontinence, but it may induce mechanical inefficiency due to alteration of the angles of force applied at the pubourethral ligament (1) (p13).

Damaged muscle/insertion of muscle. Incontinence due to a torn external anal sphincter has been reported, (1) (p75). It is possible for a torn pubococcygeus to cause urinary incontinence (3), but it would be rare with modern obstetrics. A prolapsed levator plate may also be due , at least theoretically, to stretching of the insertions of levator plate to the side walls of the pelvis.

THE FUNCTIONAL RELATIONSHIP OF URETHRAL AND BLADDER SMOOTH MUSCLE TO PELVIC FLOOR ANATOMY

The contribution of bladder and urethral smooth muscle contraction to bladder neck opening and closure is adjunctive to that of striated muscle, and is a direct function of the smooth muscle fibres pulling on their insertion points. These insertion points vary in position according to laxity in the vagina and its supporting ligaments, and as to whether or not the various striated muscles of the pelvic floor are relaxed or contracted.

Impact of the anatomical insertions of bladder and urethra on opening and closure. The urethra and bladder smooth muscle function as a unit (9). The smooth muscle contracts against its insertion points: the fibrous tissue connecting the lower 2/3 of urethra to anterior wall of vagina, pubourethral ligament and arcus tendineus fasciae pelvis laterally, pubovesical ligament anteriorly, and vesico-vaginal ligament inferiorly (1) (p19-23). It is obvious on simple examination of FIGS 5, 6, and 7a, that the position of these insertion points is not static. It varies according to the elasticity of the tissues, laxity in the vagina or its supporting ligaments, and how efficiently the forces F1, F2, FIG 3 are applied.

Opening function.
The superficial trigone extends from bladder base to the external urethral meatus (62). During bladder neck opening, it is stretched backwards by the backward extension of vagina, FIGS 5, 7a. This renders the longitudinal smooth muscle of bladder and urethra semi-rigid, so that it can be actively opened out like a trapdoor, "funnelling", FIG 5, sharply dropping the urethral resistance. Tension of the pubovesical ligament ("anterior shelf", FIG 4d, prevents the anterior bladder wall from collapsing inwards with the contraction. It also actively holds open the anterior wall of urethra.

Closure function. Again, the superficial trigone contracts, and becomes semi-rigid. This elimination of slackness allows the cresta urethralis to be pulled upwards by forward contraction of PCM, FIGS 6, 8, closing off the urethra. The now firm posterior urethral wall creates a firm cut-off point ("posterior shelf"), FIG 4e, for closure of bladder neck by the downward force F2, FIG 3. Tension of the pubovesical ligament is also important for the "kinking" mechanism of bladder neck closure. It ensures that the anterior urethral wall remains semi-rigid.

We hypothesize that the contribution of bladder and urethral smooth muscle to closure function is adjunctive to the previously described closure mechanisms, rather than primary (7). Laxity in the vagina or its supporting ligaments may not allow the semi-circular smooth muscle sphincters (7) to function efficiently.

The basis for physiological and unphysiological bladder contraction.
In this section, many of the conclusions reached by artificially distending the bladder using filling cystometry are questioned on the basis that the bladder may be distended beyond the physiological limit of the patient's continence system, giving rise to the possibility of false results. When the patient presents for testing with a comfortably full bladder, a more physiological provocation may be induced by a hand-washing test. The results from such testing confirm that bladder instability is mainly a premature activation of the micturition reflex, (54) as predicted (1).

We present the following explanation for the observed phenomena. Stretching of smooth muscle causes membrane depolarization (71). Bladder smooth muscles have characteristics which predispose to tonic contraction and urine loss, including unstable all-or-none action potentials, low-resistance pathways between cells and modification by excitatory or inhibitory nerves (72). From the foregoing it follows that bladder smooth muscle contracts tonically, whether stimulated directly, or by activation of the micturition reflex. It is known that the detrusor pressure registered on cystometry during urine flow (73) is proportional to the urethral resistance. If there is no resistance present, there will be no detrusor pressure recorded, as all the energy from the detrusor contraction is converted to flow.

We hypothesize:

1) The filling process causes the detrusor to contract tonically, i.e., it "spasms". This occurs by direct stimulation of smooth muscle, by premature activation of the micturition reflex, or both.
2) Measurement of this contraction depends on activation of the urethral closure mechanisms.i.e., if there is no urethral resistance whatsoever, then a detrusor pressure of 0cm H2O will be registered.
3) Low compliance observed during filling reflects the gradual reflex increase in the slow twitch component of the pubococcygeus/ periurethral striated muscle unit closing off the urethra in response to such a tonic detrusor contraction.
4) In patients who register a typical pattern of "detrusor instability", the bell-shaped phasic pattern generally observed, "Y", FIG 15, is not consistent with a physiological spasm of detrusor smooth muscle*, but may reflect the battle for control between the opening (micturition reflex) and closure mechanisms of the urethra acting against a tonically contracted bladder, oscillating somewhere between the "open" and "closed" positions of urethra, as demonstrated radiologically in FIG 5.
5) At the pelvic floor level, these closure/opening mechanisms are activated respectively by pelvic floor contraction, VC and O, FIG 13, W, X, FIG 14. These mechanisms work on a "feedback" system. Such systems involve a time delay, hence the classical bell-shaped curve, "y" FIG 15, seen when there is a reasonably equal balance. The rapid phasic pattern (arrows), FIG 15, is consistent with a phasic striated muscle contraction, in this instance, of the periurethral striated muscle. With large amounts of urine loss, there is an accelerator added to the system, the contraction and depression of the levator plate, FIG 4d. This would have the effect of not only "funnelling" the bladder neck and urethra, FIG5, but also greatly increasing the number of nerve impulses from "N", FIG13. The similarity between bladder instability and the micturition reflex is demonstrated directly in FIGS 15a and 15b.

* In the normal patient, the stream is continuous, indicating that the detrusor contraction is also continuous.

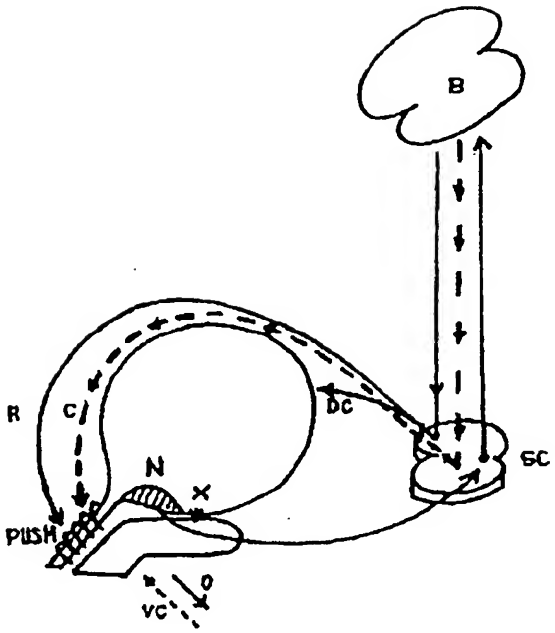


FIG 13

Schematic outline of "vaginal control" of the micturition reflex.

This is a sagittal schematic representation of bladder, urethra, vagina, spinal cord (SC) and brain (B). "N"= nerve endings at bladder base, PUSM = periurethral striated muscle, X = vesicovaginal ligament. The solid directional arrows represent the micturition reflex - afferent outflow from "N" to spinal cord and brain, and efferent flow to detrusor and urethra: DC = detrusor contraction; "R" = urethral relaxation; O = opening force applied by pelvic floor muscles. The interrupted lines represent a discrete pathway from brain to urethra which inhibits the micturition reflex, and contracts the urethra. "C" = urethral contraction. VC = voluntary closure force applied by pelvic floor muscles.

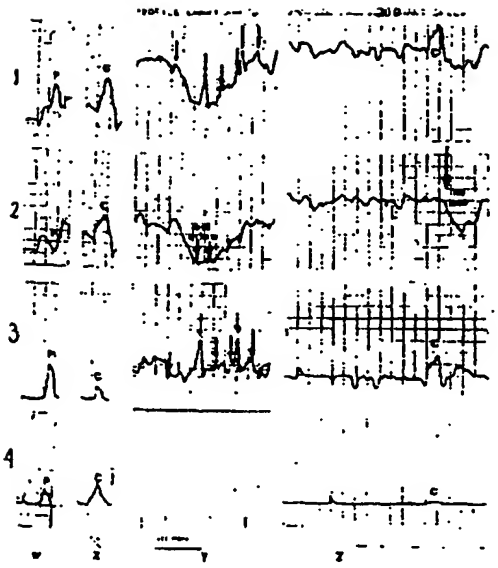
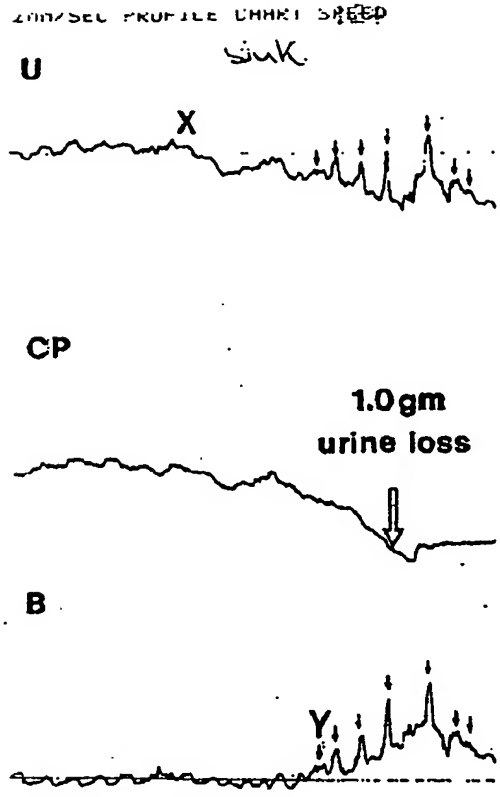


FIG 14
The effect of pelvic floor contraction on "bladder instability".
This is a urethrocystometric tracing of a patient with a full bladder.

Longitudinal Axis: 1: urethral pressure. 2: closure pressure. 3: bladder pressure. 4: EMG.

Horizontal Axis: "W": straining (P), "X": "cutting off" (C); "Y": hand washing provocation - not "holding on" - urine lost; "Z": hand washing provocation - with "holding on" - urine lost prevented despite partial activation of micturition reflex (large arrow)

Small arrows = reciprocal pressure rises in bladder and urethra;



IG 15
Uninhibited premature activation of micturition reflex with urine loss.
This is a graph of a provocative handwashing ("sink") test from a patient with symptoms of urge incontinence. "U"= maximal intraurethral pressure; "B" = bladder pressure. "CP" = electronically subtracted closure pressure. X = fall in urethral pressure; Y= rise in detrusor pressure; arrows = reciprocal increases in urethral pressure) and bladder pressure.

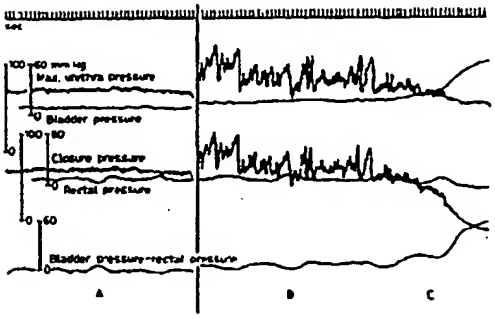


FIG 15a Instability of bladder and urethra induced by filling cystometry
A = quiescent pattern; B = commencement of urethral instability and fall in baseline urethral pressure; C = subsequent commencement of detrusor contraction. Except for the wild swings in urethral pressure, B & C are consistent with the pressure patterns obseved during normal micturition in FIG 15b.

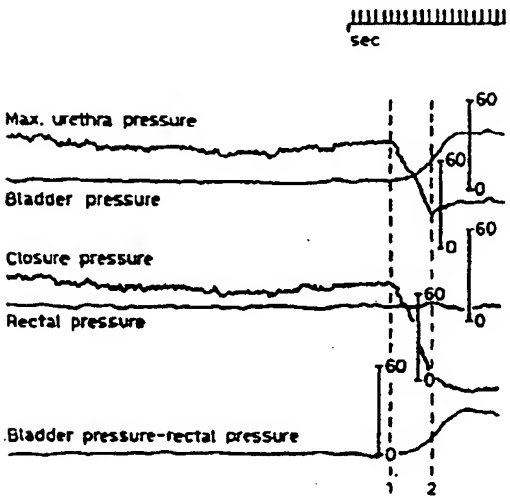


FIG 15b
Patterns of normal micturition
Rise in detrusor pressure follows a fall in urethral pressure by some seconds.

Cystometry

The total expulsive force of the detrusor during a micturition cycle is constant, (73), and does not vary either in stress incontinence, (74), or with an unstable bladder, (75).

Thus if the urethra funnels on provocative testing, i.e. is pulled open suddenly as in FIG 5, there will be a fall in urethral resistance, even to 0 cm H2O. Such a pattern was observed in 3/41 patients who lost urine on handwashing provocation (76a). In this instance, the patient will be deemed to not have detrusor instability, even though urine may actually be lost. If the body's mechanisms succeed in closing off the urethra completely, then a high pressure will be recorded in the bladder, with no observed urine loss.

It follows from this, that cystometry alone cannot meaningfully record the events occurring in the unstable bladder in all cases. It can only record the body's attempts at full or partial closure, i.e. the urethral resistance , which appears to be produced mainly by contraction of the pelvic floor (76).

Urethrocystometry, though not perfect, appears to be a superior method, as it has the capacity to also give insight into premature activation of the micturition reflex, being able to record the simultaneous changes in urethral pressure (76a).

Urine loss during handwashing or showering (FIGS 13,14, 15).

Whether or not urine is lost in patients with " bladder instability" during handwashing depends on the outcome of the struggle between the bladder neck opening (micturition reflex) and closure mechanisms, "O","VC", FIG13. The inhibitory circuit is suppressed by the act of hand-washing.

Classical patterns of a premature activation of the micturition reflex were recently demonstrated in 115 patients with a history of urge incontinence (76) presenting with a naturally full bladder for urethrocystometric testing comprising hand-washing provocation: first urethral relaxation preceded or accompanied by urge symptoms, then detrusor contraction, following some seconds later, exactly as occurs during normal micturition, FIGS 15, 15a, 15b. We hypothesize that showering or handwashing

suppresses the body's normal control mechanisms over the micturition reflex, by inhibiting voluntary contraction of the pelvic floor "VC", and by counteracting inhibition within the brain, FIG 13. The action of handwashing cannot be correlated with any of Barrington's reflexes per se. By lifting off the inhibition, however, it allows all 5 reflexes to be activated.

Anatomical correlations for urodynamic events. *Whether or not urine is lost in patients with urge incontinence depends on how successfully the vagina below bladder neck can be stretched to support the nerve endings "N", FIG2, by involuntary forward contraction of pubococcygeus muscle ("W", FIG 14) in the normal patient, or by the voluntary elevation of pelvic floor ("X", FIG 14)in the incontinent patient.*

Urethral relaxation during hand-washing provocation depends on the balance between the inhibitory efferents "C", (urethral contraction) or facilitatory efferents "R", (urethral relaxation), FIG 13. Voluntary contraction of the pelvic floor (VC), elevates the pelvic floor, FIG 4e, supports the nerve endings at bladder neck, and may reverse the micturition reflex, as demonstrated urodynamically in FIG 14, Z. Though urethral relaxation, the 1st part of the micturition, large arrow "Z", occurred, the almost simultaneous contraction of pelvic floor "C" apparently aborted the detrusor contraction, so that no urine was lost. If the prematurely activated micturition reflex predominates, and urine is lost, FIG 14 "Y". The opening force "O", FIG 13 will "funnel" the bladder neck, reinforcing the micturition reflex, as in FIG 5. Such "funneling" was noted on VCU in patients with "bladder instability" (65).

Impact of pelvic floor contraction on changes in urethral and bladder pressure.
It is mainly contraction of the pelvic floor, not the abdominal cavity, which causes simultaneous increase in urethral and bladder pressures.

At present, the reciprocal pressure changes in bladder and urethra, FIG 4c, are generally attributed to equalization of transmitted intraabdominal pressure to these organs, (14).

In a study of 163 patients subjected to the urethrocystometric handwashing test (76), the pattern of urethral pressure mirrored exactly that of the bladder in all cases, even during breathing, "b", FIG 16, 2nd even during urine loss, FIGS 14 & 15 (arrows). In 11 out of 163 patients, independent patterns of contraction were noted in the urethra, which were not reflected in the bladder. Using EMG monitoring, urethral pressure rises during straining and on initiation of various pelvic floor reflexes(77), have been previously demonstrated to be accompanied by simultaneous pelvic floor contraction (78). Not all reflexes involved in urethral closure cause simultaneous reciprocal pressure rises in the bladder, e.g. some caused by increased mental activity (79), or stimulation of anterior vaginal wall, "vM" FIG 16, do not. *Contraction of the pelvic floor muscles as demonstrated radiologically, urodynamically, and by EMG in FIGS 4-6 suggests that it may be mainly contraction of the pelvic floor which causes simultaneous increase in urethral and bladder pressures, and not straining per se, as is commonly thought.* We hypothesize that straining derives from the reciprocal relationship which levator ani has with the thoracic diaphragm and the abdominal muscles (80), (81), probably as a result of their common embryological origin (82). Hence, when the body involuntarily closes off the urethra, it does so by activating a pelvic floor contraction, FIG 4b, "S" FIG 4c. This causes a simultaneous reciprocal contraction of the abdominal musculature and thoracic diaphragm, resulting in a secondary rise in intraabdominal (and therefore, bladder) pressure. Similarly, with voluntary closure, FIG 4e, "C" FIG 4c. It is implicit in the equalization theory that the same force which can compress the urethral tube, can also deform and push down the pelvic floor. This is a passive concept, and is generally accepted. However, it is clear on simple observation of FIGS 4b, 4c, and 4e, that the pressure rise during lifting of the pelvic floor and organs on "cutting-off" is similar to that seen during depression of the pelvic floor and organs on straining. Furthermore, EMG recording, FIG 4c confirms the radiological impression of simultaneous pelvic floor contraction.

If the intraabdominal pressure equalization theory were the sole explanation for the pressure rises noted, then there would be no need either for pelvic floor contraction, or for independently innervated urethral contraction. "Vm", FIG 16.

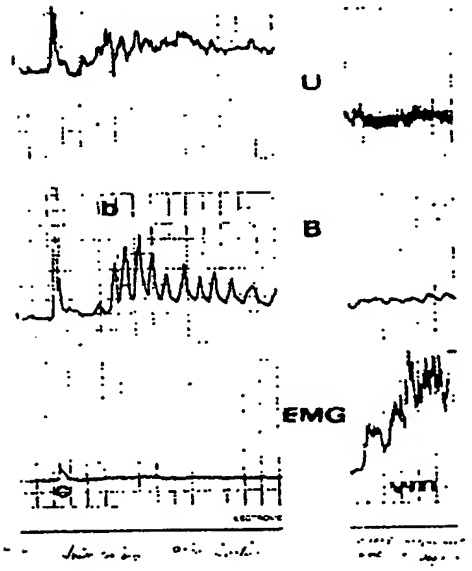


FIG 16
Examples of coincident and independent urethral contractions.
U = midurethral pressure; B= bladder pressure; EMG = electromyogram recording in anterior part of vagina. c = coughing "b" rapid breathing; vM = rapid stimulation of anterior vaginal wall.

False detrusor dyssynergia.

The urethra may contract independently of the bladder.

The signal to relax the urethra may be counteracted by either voluntary, "cutting-off", "C" or reflex contraction of urethra, "pushing", "P", FIG 14, often to the point where there is a relative obstruction to flow giving rise to a false diagnosis of "detrusor dyssynergia" in the absence of neurological disease (78).

"Better"explanation (59) of some previously discussed phenomena by the Integral Theory.

Ultimately, according to this theory, all associated phenomena of "detrusor instability", even in some patients with neurological damage, can be traced to a defect somewhere along the circuits schematically represented in FIG 13.

Some examples*

Stimulation of a detrusor contraction by effort (19), is explained according to(1) by inability of the forward portion of the pubococcygeus (PCM) to adequately immobilize the vagina below the bladder neck, and so prevent stimulation of the nerve endings by the posterior movement instigated by the levator plate during the bladder neck closure mechanism. The mechanism for this is demonstrated in FIG 12b. Inability of PUL to restrain the vagina may result in sudden massive "funnelling", also resulting in activation of the micturition reflex. In pregnancy, stress and urge incontinence (83), and symptoms of defective opening, (84), are explained by the pregnancy hormones, relaxin, and prostaglandin inducing laxity in the connective tissue of vagina and/or its supporting ligaments. Return to continence after confinement in 95% of patients (83) is consistent with this explanation. Symptoms of deficient opening, as well as high residual urine are explained as follows: laxity in the posterior fornix of vagina inhibits the opening action of the longitudinal muscle of the anus, resulting in a deficient number of afferent impulses from the nerve endings at bladder base, "N", FIG 13, so that the strength and length of detrusor contraction is likewise suboptimal. *This may explain why the cystometric projections (73) used to calculate work of the detrusor muscle are not applicable in patients with high residual urine.* According to (1), high residual urines are an end point of deficient emptying, and both result from deficient anchoring of the posterior fornix of vagina (cf posterior fornix syndrome, part IV). The symptom of "stopping and starting" associated with repeated straining is explained as an attempt to further stimulate "N" by pulling the bladder neck down and back. FIG 4b. Urge symptoms due to cystocele/vaginal vault prolapse are explained by causing "dragging" on the vagina at bladder base, or because of concomitant laxity in the supralevator vagina. Both may stimulate the nerve endings at bladder base. A new incidence of urgency following bladder neck elevation may be explained by the elevated vagina creat-

ing upward pressure on the nerve endings at bladder base, thus causing premature activation of the micturition reflex. Thus the very high incidence of "detrusor instability" in the group of operative failures reported (19) may well have been a self-selected group, i.e. the operation failed because of the excessive elevation causing the new incidence of "detrusor instability". Inflammation causes oedema, and therefore stimulation of the nerve endings in the area. Neural spinal cord disease such as Multiple Sclerosis acts by blocking the efferent inhibitor side of the urethral reflex in the spinal cord. This effectively prevents the action of "C" and "VC", FIG 13. According to the Integral Theory (1) symptoms of frequency, urgency and nocturia at period time may be due to prostaglandins causing laxity of the connective tissue in transverse cervical and uterosacral ligaments, possibly analogous to cervical softening just prior to labour (85). This interferes with the ability of the pelvic floor muscles to create a drum-like support by vagina of the nerve endings at bladder neck. Similarly urinary incontinence and nocturnal enuresis in children is possibly explainable by a congenital defect in the pubo-urethral ligaments or collagenous connection to pubococcygeus muscle (PCM), preventing adequate vaginal tensioning, and therefore support for the nerve endings, and even closure. A similar pathogenesis could explain the stress/ urge incontinence often seen in young women,(86).

* many examples, such as why the detrusor contraction curve is phasic have already been presented in the text. Others follow in parts II,III, and IV.

Correspondence:
PE PAPA PETROS
14A Surgicentre
38 Ranelagh Cres
South Perth, WA 6151
AUSTRALIA
Fax 61-9-4743766

ORIGINAL ARTICLE

PART II. THE BIOMECHANICS OF VAGINAL TISSUE AND SUPPORTING LIGAMENTS WITH SPECIAL RELEVANCE TO THE PATHOGENESIS OF FEMALE URINARY INCONTINENCE

Authors: PE PAPA PETROS, MB BS Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT

The vagina is presented as a living organ, whose structure, elasticity and tensile properties may be altered by age, pregnancy, parturition, and surgery. An alternative concept for urodynamic pressure measurement is introduced, based on the Integral Theory (1: p63-67), whereby forces creating the pressure in the urethra as measured by a microtransducer, actually derive from the periurethral striated muscle (PUSM). As pressure = force/area, given that the muscle force for a given contraction is always constant, dynamic pressure variations during manoeuvres such as coughing, straining and 'cutting-off' will vary according to the area of the urethral cavity over which the PUSM forces are applied. This area varies according to what degree of urethral closure is attained by the closure muscles acting on the vagina. The relationship of vaginal tension to these forces is analysed with special reference to the stress extension curve of vagina, and also, the various anatomical defects as defined by the proposed Integral Theory.

INTRODUCTION

In (1), the vagina is presented as a living organ, which cannot regenerate, and whose structure, elasticity and tensile properties may be altered by age, pregnancy, parturition, and surgery. The vagina is assigned a primary role as a transmitter of muscle contraction in urethral and bladder neck closure, and as a structural supporting membrane for the nerve endings at bladder neck. We hypothesize that the "fine-tuning" of the critical tension necessary to allow this dual function involves a complex feedback mechanism between the slow twitch striated muscle fibres of the pelvic floor area, and the brain.

If the vagina is lax, its structural supporting function may be lost. Also, striated muscle contracts over a fixed distance (71). A lax vagina means that the contraction of the muscle inserting into it is dissipated (87). Therefore we consider analysis of the physical, biochemical, and biomechanical properties of vagina to be essential to the understanding of the pathogenesis of female urinary incontinence.

Effect of age and hormones on the structural components of the vagina.

Age and hormones may cause laxity and therefore, loss of structural integrity of the vagina and its supporting ligaments. More advanced age may cause shrinking of residual vagina after surgery, as well as scar tissue, resulting in the tethered vagina syndrome (1) years after an initially successful operation. The pubourethral ligament and the collagenous connective tissue insertion ("glue") between vagina and the pubococcygeus muscle may also weaken with age, causing severe urinary and even faecal incontinence. What is commonly described as the "vaginal fascia" has been histologically demonstrated to consist mainly of smooth muscle (88). The fascial plane of vagina is actually not a well defined structure (88), has very little strength, and is actually a part of the fascia endopelvina, (88). Structurally, the vagina is weaker than other tissues such as aorta (94)(95). Its strength therefore, must be related to the structural compo-

nents within its smooth muscle, fascial connective tissue, and the epithelial cells per se.

The mechanical function of connective tissue depends on the structure of the extracellular matrix, and the orientation of the collagen fibres within that matrix (89)(90). The relative proportions of the various glycosaminoglycans influences the mechanical properties of the tissue. e.g., chondroitin 6 sulphate interacts more with collagen molecules than keratan sulphate, which interacts more than chondroitin 4 sulphate etc. During pregnancy, there is a marked change in the ratio of hyaluronic acid to dermatan sulphate, resulting in marked distensibility of the cervix (91) (92). Conversely, the increased content of dermatan sulphate with age, (93) renders the tissue less distensile.

Collagen fibrils appear to reinforce the ground substance much in the same way as glass or carbon fibres provide reinforcement in synthetic composite materials (89). The condition for effective reinforcement is expressed in terms of "critical length" (89) a function of fibril radius, the stress at which fibrils break, and the shear stress exerted by the fibril. A decreased critical length (scurvy) or increased critical length due to increased cross linking of collagen (ageing) may actually impair reinforcement (89). During pregnancy, part of the mechanism for softening in experimental animals may be due to the effect of relaxin inhibition of lysyl oxidase, the main collagen covalent cross-bonding enzyme (92). Once the tensile limit of a tissue is reached, individual fibrils may break, so that the others become overloaded. In this way, the tissue may fail catastrophically (89). Though the collagen fibrils themselves increase in strength with age, a net loss of tissue strength with age has been demonstrated by direct testing (94). The standard deviation of the physiological age of tissues is approximately 25% between the ages of 40 and 80, i.e. a patient with a calendar age of 60 years may have tissues with a physiological age ranging in extreme circumstances between 30-90 years, but more generally between 45 and 75 years. *On this basis alone, the propensity for surgical failure due to poor strength/elasticity of vaginal tissues, present and future, is huge.* Data of tissue breaking strain, (94) indicates that the vagina does not have strong structural components when compared to other tissues of the body, e.g. skin, artery, tendon etc (94) (95).

Mechanical influences aside, we attribute the appearance during pregnancy of stress and urge symptoms (83), and symptoms of defective emptying (84), to hormone induced laxity (1) (p77-78) of the vagina. This laxity is mostly reversible (83). Symptoms of stress and urgency, during pregnancy can often be alleviated by insertion of a ring pessary. This stretches the vagina, removes laxity, and re-creates the tympanitic membrane essential for opening, closure , and support of nerve endings at bladder base. Perimenstrual urge/stress symptoms may be ultimately caused by prostaglandins and other hormones loosening the cardinal and uterosacral ligaments along with the cervix, (defect no 4, classification, FIG 2), possibly analogously to what occurs during cervical ripening (91). The above manifestations are consistent with the concept of vaginal laxity causing various symptoms of urinary incontinence (1).

Structure and function of ligaments.

The mechanical properties of the various tissues are related to the differences in alignment of the collagen fibres. Skin is weaker than tendon because fewer fibres are oriented in the direction of loading (90). Structural orientation varies in different ligaments depending on function. Although most ligament collagen fibres are nearly parallel, some have a non-parallel orientation. The strength of collagen is a function of its inter and intra molecular cross-bonding (96), with identifiable increases in particular types of cross-linking. Load bearing ability of collagen increases with age (96). The biochemical processes of aged collagen are complex, and include an oxidative mechanism (97). Loss of elasticity in human tissue occurs after the age of 40 (96), as can be seen by comparing FIG 7a with FIG 7b.

When the ligaments are unloaded, collagen fibres have a wavy configuration. When loads are imposed, low loads are sustained until the fibres oriented in the direction of loading, straighten out. At this point the straightened fibres sustain loads in the physiological range. This also provides a "shock absorption" function for vagina and urethra FIG 7a. Elastin allows a

tissue deformed by stretching to return to its original state on release of the deforming force, FIG 7a. *Thus the elasticity of vagina and urethra is a low energy method of retaining urethral closure in the normal patient.* We believe the acute rise in detrusor pressure at the end of micturition as being due to this restoring force.

Structural failure.

The elastic component of vagina is susceptible to rupture with relatively light loads. Therefore any stretching of vagina during surgery must be carried out with care. Deformation to failure depends on the qualities of collagen and elastin. Elastin fibres display great elongation (more than two times the original length when low loads are imposed). With increased loads, they suddenly become stiff and rupture abruptly without deformation (92). On extension, collagen fibre become stiff and reach their yield point, generally without breaking. Therefore, over-extension of vaginal tissue may principally destroy the elastin content of the tissues. Once the elastin has been broken, say by excessive elevation of vagina or by childbirth and subsequent herniation, then the collagen fibres align along the lines of force, (gravity). In the urethra, this may cause laxity, a low urethral pressure (1), and 'constant seepage of urine'.

Biomechanical properties of vagina.

Advancing age weakens the structural integrity of vagina, and changes its stress elongation curve. This narrows the margin for error with incontinence surgery.

The vagina has a dual role. It structurally supports the nerve endings at BN, and transmits the contractile forces from PCM and LP, FIG 17 generated by the pelvic muscles. The stress elongation curve of vagina is almost identical to that of the trigone in the urinary bladder (94), indicating that the trigone will be stretched synchronously with the vagina on application of a force.

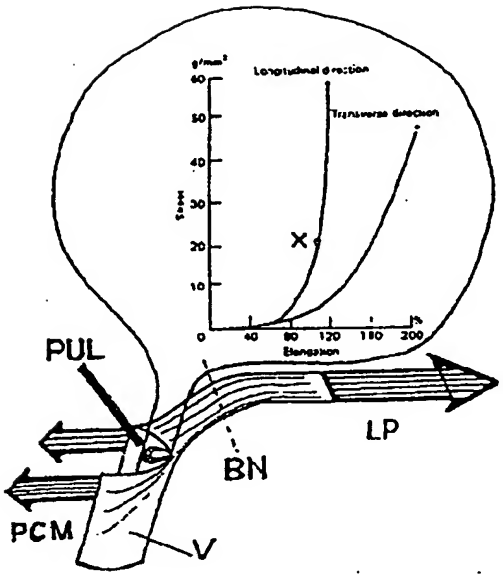


FIG 17
Differential extension of vagina.
This represents a standing lateral sagittal section of the bladder and its anatomical supports. PUL = pubo urethral ligament; BN = bladder neck; LP = levator plate; V = vagina; PCM = pubococcygeus muscle; Inside the bladder is a stress extension curve of vagina. "X"= stretch limit.

Point (X), FIG 17, represents the point where the vagina can stretch no more and becomes a rigid transmitting membrane. Any force applied beyond point (X) is then faithfully transmitted to whatever the vagina is connected to, i.e. the lower 2/3 of urethra, and to bladder base. The initial elongation limit of urogenital tissues (to point X, FIG17), is 20%-35% of the ultimate strength; initial elongation = 60%-80% of the ultimate elongation (97). The ultimate tensile strength of the urogenital tissues is greatest between 10 and 29 years, but by 50 to 79 years the strength has decreased to about 60% (98).

Function of differential vaginal tension.
Less extensibility in the longitudinal axis of vagina ensures that a semi-rigid " spine" . FIG 17a, in the posterior urethral wall is quickly created, ensuring that opening and closure of the urethra may proceed efficiently.

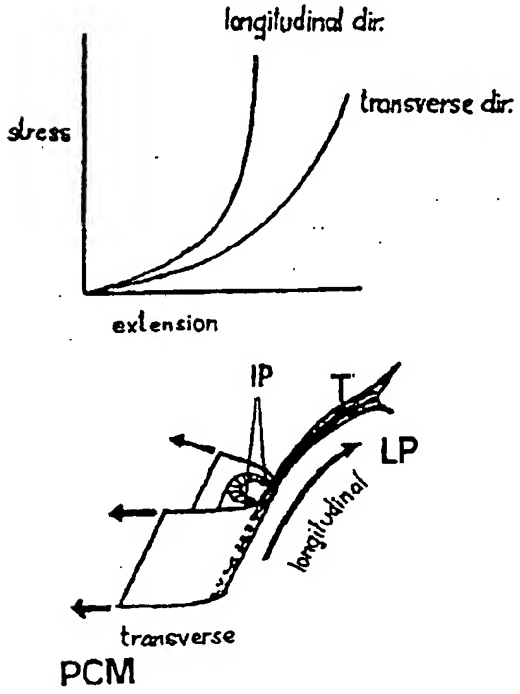


FIG 17a
How differential extension of vagina aids opening and closure of urethra.
Standing sagittal section. LP = levator plate; PCM = pubococcygeus muscle; T = superficial trigone; IP = insertion points of periurethral striated muscle.

Like other urogenital tissues (97), the vagina has a differential elongation longitudinally and transversely. Tension in the longitudinal direction, is achieved by contraction of the levator plate (LP). This is radiologically demonstrated in FIGS 5, 6, 7a, 7b. Tension in the transverse direction, is achieved by forward contraction of the pubococcygeus muscle (PCM), pulling the vagina forward. This is radiologically demonstrated in FIG 6, where the midurethra is obviously pulled forward during straining, "S".

Because point "X", is reached earlier in the longitudinal direction, it converts the posterior wall of urethra into a semi-rigid structure, so that it can now be pulled forward by PCM to close urethra, or pulled down for opening/closure by subsequent contraction of LMA, i.e. the urethral tube is opened and closed antero-posteriorly along most of its length, as demonstrated in FIG 5. *This is a much more efficient arrangement for a sphincter mechanism than circular closure at a singular point.*

As the urethra lengthens during closure, FIG 3, so does it become narrowed. This applies especially to the upper 1/3 of urethra which has no vaginal attachments. According to the law of Laplace, the tension acting in the lumen increases, aiding closure.

Biomechanical effect of changed elasticity.
Decreased elasticity means that the point on the stress extension curve where the force is transmitted, instead of being absorbed by stretching the elastic components, is reached much earlier. Vaginal scarring may vastly accelerate this process.

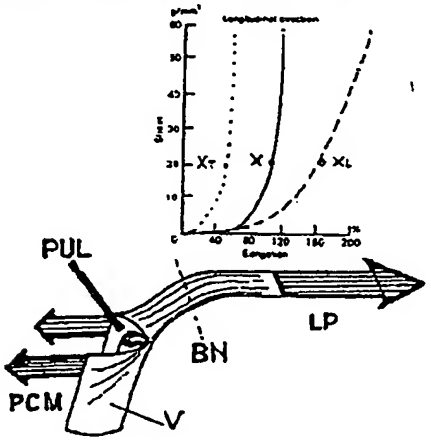


FIG 18
Influence of vaginal elasticity on muscle force transmission.
This is a stress extension curve of vagina. XT = poor vaginal elasticity, e.g. from scarring at bladder neck; X = normal elasticity; XL = vaginal laxity; PUL = pubourethral ligament; BN = bladder neck; LP = levator plate; V = vagina; PCM = pubococcygeus muscle.

In FIG 18, low vaginal elasticity, as in curve XT, means that the point of transmission is reached much

earlier along the elongation axis. This pattern is typically seen in the "tethered vagina syndrome". If the vagina is lax, as in curve XL, a significant amount of the muscle contraction is wasted in extending out the laxity. Point X may never be reached, so that urethral closure may not occur.

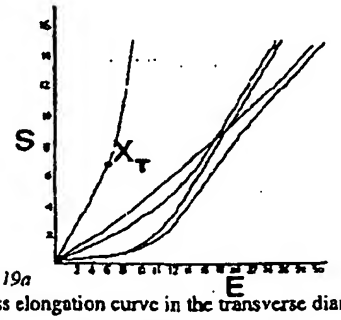


FIG 19a
Stress elongation curve in the transverse diameter of vagina in the area of bladder neck in five postmenopausal patients with stress incontinence, as measured "in vivo", by a prototype elastometer. S = force applied; E = extension of vaginal wall.

This is an actual stress-elongation graph taken in the transverse axis of vagina in the region of bladder neck, in four SI females (to the right in the diagram) and in a patient with the "tethered vagina syndrome" (XT), using the prototype elastometer instrument depicted in FIG 19b. Very little stretching of the vagina would be needed to reach (XT) in the patient with tethered vagina. A bladder neck elevation operation would most likely worsen this patient's symptoms, by removing any remaining elasticity from zee, FIG 3. By the same token one could proceed to such an operation in the other 4 females with confidence.

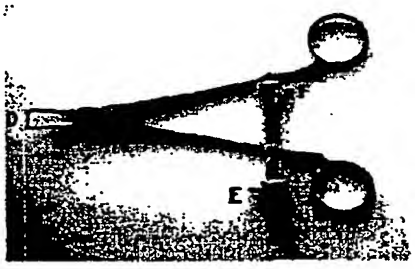


FIG 19b
Prototype elastometer. D = distance between hooks; E = extension distance; F = variable force.

Lose (99) demonstrated 2 distinct patterns, similar to FIG 19a on measuring urethral elasticity. We explain his results as being secondary, and dependent on, how much the vagina was stretched by the catheter within the urethra, given our concept that the smooth muscle extension of the bladder/urethra unit is ultimately limited by their insertion points into the vagina.

How vaginal laxity limits the effect of pelvic floor exercises.

It is clear from examining "C" FIG 6, how learning the voluntary closure mechanism with pelvic floor exercises can stretch the vagina upwards, facilitating point X, FIG 17, being reached during closure with a lax vagina. As striated muscle contracts over a finite distance (87), however, there is a limit as to how much extra efficiency can be squeezed out of the system. Even with patients who are greatly improved, further age-related loss of elasticity inexorably results in a return of symptoms. Given the evidence presented here as concerns the urethral and bladder neck closure mechanisms, and the important role of the pelvic floor muscles therein, it would appear that pelvic floor exercises incorporating straining/pushing in the normal patient would also be essential in prophylaxis, something not presently recognized by physiotherapists.

Visco-elastic "creep".

Over a period, the muscle forces acting on the vagina have the potential to loosen any surgically imposed tension.

In this context, visco-elastic "creep" is defined as the gradual flow of a material under a sustained load. Each tissue will have its limit, e.g. the "creep" limit for the urinary bladder of dogs and rabbits is 60% of the ultimate strength of the tissue (95), whereas the initial elongation limit is only 20-35% of the ultimate tissue strength (94). This may explain why it has evolved that in vaginal surgery, much larger tracts of vagina are routinely excised than would appear necessary (cf surgical recommendations, part III). This technique, without realizing it, anticipates the process of visco-elastic "creep".

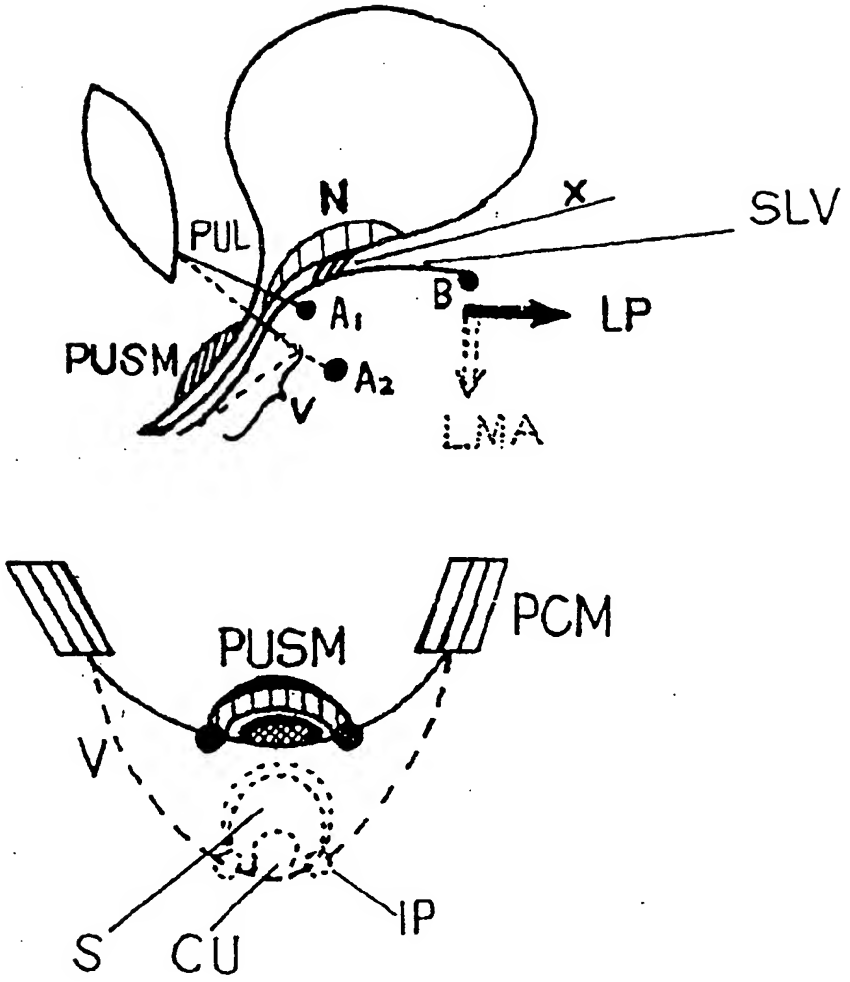


FIG 20

The mechanics of lowered pressure transmission ratio.

vaginal laxity (broken lines), may result in failure to achieve the "closed" position (solid lines) during coughing or straining. The urethra remains relatively "open" (broken lines). Thus the dynamic increase in pressure from PUSM is exerted over a larger area "S". As the contractile force is always constant (100), a low transmission ratio signifies that "CU" is not tightly apposed to PUSM at the point of measurement.

Upper diagram represents a sagittal section of the anterior wall of vagina, urethra, and bladder. V = vagina underlying the lower 2/3 of urethra; PUL = pubourethral ligament; PUSM = periurethral striated muscle; N = nerve endings at bladder base; X = vesico-vaginal ligament; SLV = supralevator vagina: A1 = vaginal attachment of PUL; A2 – the same attachment stretched by contraction of LP (levator plate) and LMA (longitudinal muscle of the anus); B = insertion of uterosacral and cardinal ligaments. Lower diagram represents a transverse section of the mid urethra; PUSM = periurethral striated muscle; V = vagina; IP = insertion points of PUSM; CU = cresta urethralis; S = space between PUSM and CU (the area over which PUSM contracts); PCM = anterior portion of the pubococcygeus muscle. The broken lines 'open' position; solid lines: closed position.

"Creep" is explainable in terms of the initial distension being due to the stretching of collagen and elastic fibres, subsequent rearrangement being due to the molecular adjustment of the ground substance to this increased load. We attribute the gradual return of ability to micturate following urinary retention subsequent to a tight vaginal repair, or bladder neck elevation procedure to the visco-elastic "creep" equalizing the tissue tension in vagina between USL and external urethral meatus, relieving tightness, and permitting F2, FIG 3, to once more actively open the bladder neck. *We believe that overdistension of smooth muscle is unlikely to be a major mechanism in the causation of post-operative urinary retention. as smooth muscle, unlike striated muscle, can function effectively over a large range of distension lengths (71).* Similarly, transient urge symptoms seen after vaginal repair are explainable by a temporarily excessive tension from below stimulating the bladder base nerve endings (1) (p55), with "creep" explaining the subsequent release of tension, and therefore, relief of symptoms.

Loss of urine with repetitive coughs.

Tissue hysteresis inhibits the restorative elastic closure force of urethra, facilitating urine loss with repetitive coughs.

We attribute loss of urine subsequent to initial non-productive coughing to a hysteresis factor preventing adequate recoil of the elastic structures PUL, SLV, V, FIG20. The space "S", FIG 20, increases with every cough.

The dynamic interpretation of muscle force as reflected by pressure transmission ratios.

It is our concept that pressure readings have an important role in the dynamic assessment of the various closure mechanisms, as they have the potential to measure force. Pressure = force/area.

According to (1), the urethral "cavity" is subjected to three different forces originating from three different muscles during opening/closure, FIG 3. In sequence (LP) moves backwards, then (PCM) forwards and finally (LMA) downwards. These events instantaneously alter the intraurethral area on which the periurethral striated muscle acts.

Pressure = force/area. Vaginal laxity increases the intraurethral area ("S" FIG20) over which the striated muscle force ("PUSM" FIG20) acts; i.e. pressure transmission ratio will be diminished during certain manoeuvres if the muscle forces cannot close the urethra, because the force of muscle contraction is always constant (100). In the normal patient, there is a degree of over-compensation by the muscle forces activating the involuntary closure mechanisms, hence pressure transmission ratios well in excess of 100% are frequently recorded on coughing.

Vaginal laxity, (broken lines FIG 20), increases the space "S". Therefore (PUSM) contraction is exerted over a relatively larger area and this is reflected in a negative pressure transmission ratio, as noted for straining, coughing, and "cutting-off", FIG 21a.

Interpretation of PTR changes according to various manoeuvres.

The pressure transmission ratio (PTR)is a potentially powerful tool for estimating the relative diminution of muscle force transmission caused by vaginal laxity. When combined with knowledge of the directional force of pelvic muscle contraction, F1 F2, FIG3, and observed laxity in positions 1-5 of vagina,FIG2, PTR may assist in the diagnosis of specific anatomical defects as per the classification.

NOTE: In the following graphs, "pushing" (P) is synonymous with "straining" (S).

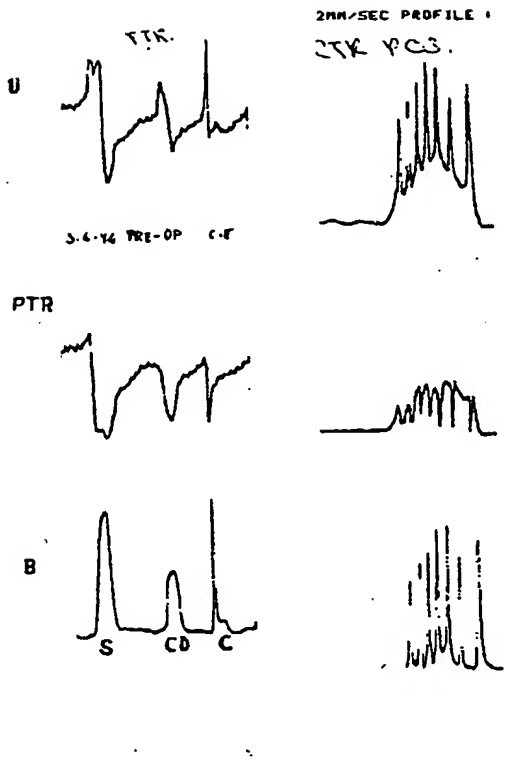


FIG 21a
Pre-operative pressure transmission ratio in the supine position.
on pushing (S), "cutting-off" (CO) and coughing (C). U = mid-urethral pressure; B = bladder pressure; PTR = pressure transmission ratio. POS CTR indicates that the transducers were oriented posteriorly.

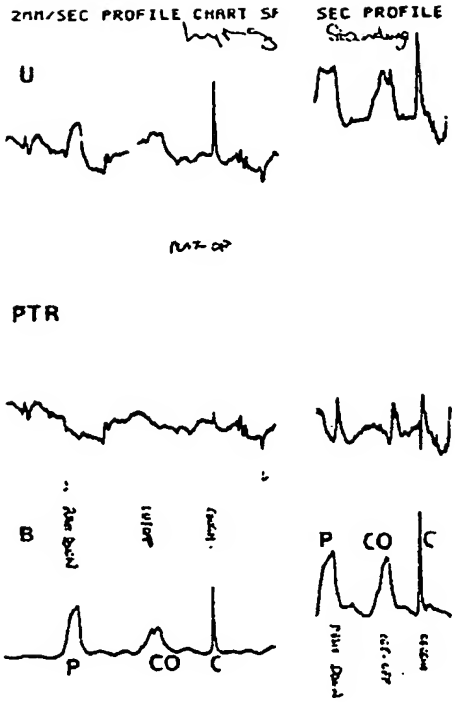


FIG 21b
Postoperative pressure transmission ratio in the supine and standing positions.
U = mid-urethral pressure; B = bladder pressure; PTR = pressure transmission ratio P = "pushing "(Valsalva): CO = "cut-off"; C = coughing.

The dynamic interpretation of urethral pressure readings is further demonstrated in FIGS 21a and 21b in a patient who underwent the IVS (intravaginal slingplasty procedure). This operation tensions the suburethral vagina, and creates an artificial pubourethral ligament (PUL).

In the preoperative graph, PTR, FIG 21a, is negative during 'pushing', "cutting-off", and coughing, i.e. the vagina is so loose, that PCM cannot close the urethral space "S", FIG 20.

In the postoperative graph, FIG 21b, in the supine (lying) position, PTR during coughing (C), has reverted to normal, but not PTR on "pushing" (P), which is slightly negative. In the standing position, however, PTR on "pushing" (P) has now become positive. Hypothesized interpretation: In the standing position, the levator plate (LP), FIG 17a, is contracted, and so the vagina is already partly stretched longitudinally. In the supine position, LP is relaxed. Some of PCM's energy is expended in stretching that part of vagina normally stretched by LP in the longitudinal axis, FIG 17a. The work performed by a muscle for a given nerve stimulus is constant (100). Therefore less energy is available to close off the urethra which remains relatively open. Hence a low PTR is recorded.

Paradoxical leakage

is defined as leakage on bending , which occurs at a lower pressure than coughing, (which does not provoke leaking). Paradoxical leakage is explainable by a prolonged active stretching downwards of the anterior vaginal wall by the LMA due to low elasticity in the ZCE, or deficiency in PUL. FIG12b. This actively pulls open the urethra/bladder neck. As such it is not strictly stress incontinence. an essentially passive concept, even though the urine loss is provoked by effort.

Hitherto, leakage on bending over. or getting up off a chair has been generally considered as stress incontinence. We have found that many patients with pubourethral defect, or with the tethered vagina syndrome did not have SI on coughing, yet leaked at a far lower pressure on bending or standing. (1) (p63-67). With the tethered vagina syndrome, the cough stimulus, FIGS 21a, 21b, 22, lasts no more than half to one second. This is just sufficient to stretch vagina rapidly to just short of point (XT), FIG 18. This leaves just sufficient elasticity in the zce. FIG 3, so that F1 and F2 may proceed independently to close off urethra and bladder neck. Straining lasts three to four seconds, point X is reached and maintained, so that in patients with scarring at ZCE or deficient PUL , FIG3, F2 may now oppose F1. The bladder neck is pulled open on being given the signal to close at a lower pressure than during coughing, "paradoxical leakage".

The effect of contraction time on the pressure transmission ratio.

We hypothesize that the muscles LP, PCM and LMA exert their action in this sequence. The contraction time of this sequence, and its interaction with the various anatomical defects 1-6, FIG 2, determines the symptomatic presentation, and the pressure transmission ratio (PTR) which is registered.

During coughing, FIG 21b, left-hand graph, PTR is positive for coughing (C), but negative for straining (P). During coughing, the force from LP FIGS, 17a, 18, is exerted only over half to one second. Point X is reached first in the longitudinal axis, then later in the transverse axis. LMA is minimally activated, so that space "S", FIG20, remains small. The residual elasticity in the transverse diameter of vagina therefore allows the PCM (F1) to move the cresta urethralis forward a fraction later to close off the urethra, independently of LP. During straining, however, LP/LMA (F2) is exerted over three to four seconds so that if F1 cannot effectively close the urethral cavity, the posterior urethral wall is pulled open like a trapdoor, enlarging the urethral "cavity", and causing PTR for straining, P (FIG 21b), to become negative. During "cutting-off, "CO", the pelvic floor, rectum, vagina and bladder neck are lifted upwards and forwards, assisting point X, FIG17 to be reached in both axes, so facilitating urethral closure. This "stretching up" action on the vagina is morphologically demonstrated in FIGS 4e and 6. During "cutting-off. "CO" (FIG21b), F2 is not activated at all. F1 closes the urethral space, so that PTR for "CO" is positive, even though the contraction lasts 3-4 seconds.

Significance of a low cough transmission ratio in SI.

A lax vagina delays urethral closure, increases the area over which the striated muscle force is exerted, therefore decreasing the cough transmission ratio.

We have demonstrated how the "pinch test" (1) (p33-35) may increase the cough transmission ratio (CTR). Similarly, injection of distending fluid periurethrally may tension the insertion points (IP) of periurethral striated muscles sufficiently to allow isometric contraction of those muscles, also increasing the CTR, FIG 10. It follows that a low CTR, FIG 21a, probably indicates a lax suburethral vagina in the presence of an intact PUL. If so, such a patient has a high possibility of cure by vaginal repair. We believe that peri-urethral GAX collagen injections work similarly to the process in FIG10, i.e., taking the laxity out of the transverse diameter of vagina decreasing "S", FIG20, and also, anchoring the insertion points (IP) of PUSM. FIG20.

Significance of a high cough transmission ratio in effort/stress incontinence.

The sequence of pelvic floor muscle movements, LP, followed by PCM, then LMA, means that over the 1/2 to 1 second over which these movements occur, the contribution of LMA is minimal, i.e. any situation which facilitates extension of the posterior wall of urethra in the longitudinal axis may create a high

cough transmission ratio. This may occur even in the presence of a lax suburethral vagina, especially if there is a deficient PUL fulcrum preventing the separate actions of PCM and LP.

We have regularly noted that CTRs of 100% are frequently found in incontinent patients with obviously lax suburethral vaginas. We explain this by loss of the PUL fulcrum function, FIG 12b. If PUL is loose, then differential LP contraction during the cough pulls the vagina back sufficiently to tension it longitudinally. This movement anchors the (PUSM) insertion points, FIG 8, ensuring efficient contraction and a high CTR* (1) (p37-39). Patients with non-stress non-urge incontinence(1) (69-70), or with the tethered vagina syndrome (1) (63-67) often did not lose urine on coughing. They did lose urine on getting out of bed, or off a chair. We explain this as being due to subsequent prolonged pelvic floor contraction opening the vagina (and therefore urethra) like a trapdoor, FIG 20, broken lines, "S". The marked elongation of vagina possible with a PUL defect is obvious in FIG 12b.

* Despite the high CTR, urinary leakage may still occur, as water-tight closure requires elevation of the crista urethralis and tightening of the vagina by the PCM, FIG 8.

Adjunctive concept for aetiology of stress incontinence.

We suggest that stress incontinence may not be entirely a passive process. Given the sequence of muscle movements, LP, PCM, LMA, FIG 2, then if PCM cannot be activated, the system is thrown from the "active closed" to "open" position, i.e. it is likely that the urethra may be actively opened, at least in part during stress, by the events occurring in FIG 12b.

Positive Valsalva PTR in the incontinent patient.
This may suggest a posterior fornix defect.

We have recently performed a Valsalva PTR test in 10 asymptomatic nulliparous controls, and 163 female patients with urinary incontinence (unpublished data). All females were tested with a full bladder. According to our results, the PTR straining test was mostly positive in control patients, and mostly negative in incontinent patients with a full bladder. This is consistent with previous reports (102). However, we found that PTR on straining was positive in 21 incontinent patients. The incidence of hysterectomy in this group was 14/21, i.e. 66%. Using a two sample test of proportions, $p = .0008$ (< 0.001); i.e. hysterectomy seems likely to be a causative factor. One explanation for this may be according to (1) p 71-73), that transverse suturing of the vaginal vault during hysterectomy may cause laxity in the posterior fornix, so that the LMA contraction can no longer properly tension the supralevator vagina, FIG 2. This may lead to defective bladder neck opening and/ or closure.

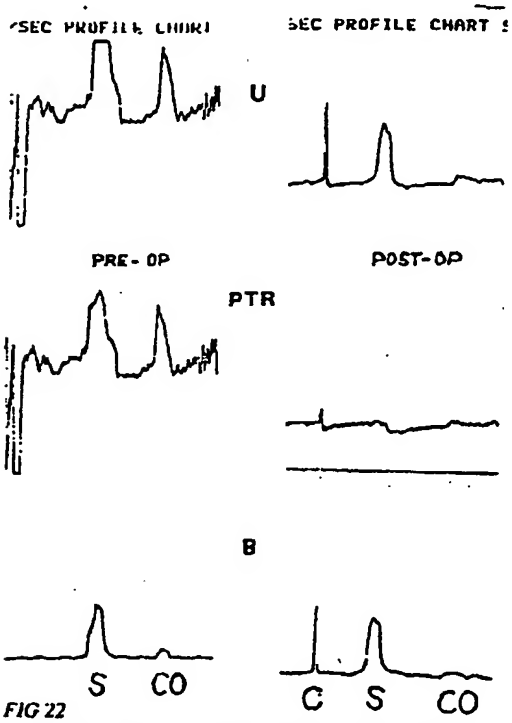


FIG 22
Change in PTR following posterior fornix repair.
This is a pre- and postoperative graph of a patient with stress and urge incontinence due to a posterior fornix defect who was cured by a posterior fornix repair S = strain; CO = "cut-off"; C = cough; B = bladder; U = urethra; PTR = pressure transmission ratio.

FIG 22 indicates how an incontinent patient cured by a posterior fornix repair (part IV), this issue), converted a positive PTR to normal.

Interpretation of the valsalva PTR test according

to (1).

In FIG 22, pre-operatively, PTR on straining (S), in the lying position, is positive, a pattern found frequently, but not always, in patients with urinary incontinence due to a posterior fornix defect, (defect no 4, FIG 2). This patient was surgically cured by making a 4 cm horizontal incision in the posterior fornix of vagina, stretching it up longitudinally, and suturing it side to side. Postoperatively, the PTR has converted to being only slightly negative. Interpretation: preoperatively, LMA contraction was weak because of laxity in the uterosacral ligaments. "V", FIG 20, could not be pulled open by LMA, "S" remained narrowed, and PTR was recorded as positive. The operation tightened the uterosacral ligaments, LMA contraction returned to normal, "V", FIG 20, was pulled down on straining, "S" increased, and PTR was recorded as normal - slightly negative. PTR "C" (coughing) FIG 22, is positive, because vaginal stretching is much less over 1/2-1 second, so that the urethra is not opened significantly. PTR during "cut-off" is positive throughout, due to a different mechanism which elevates the vagina, best demonstrated in FIG 6.

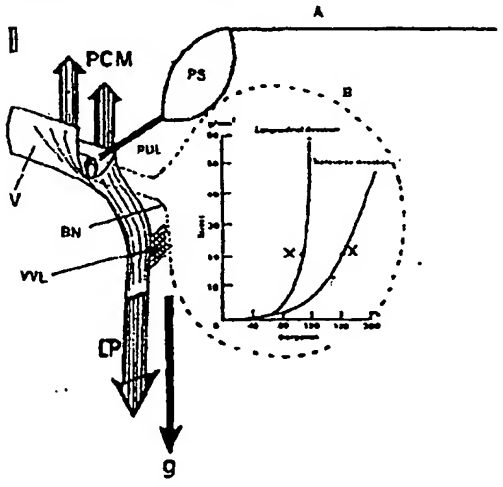


FIG 23

The urethral closure system has limited muscle strength.

This represents a sagittal section of a patient lying in the supine position. A = rectus sheath; B = urine-filled bladder; g = force of gravity (inertial load) acting on the full bladder; VVL = vesicovaginal ligament; labelling otherwise as in FIG 17 stress - elongation curve of the urogenital tissues is contained inside the bladder.

Relationship of cough transmission ratio to bladder volume, vaginal laxity, and urge incontinence.

Increasing bladder volume increases the inertial load "g" on the urethral closure muscles for the 1/2 - 1 second duration of a cough. FIG23. This delays urethral closure, increases the area over which the striated muscle force is exerted, thereby decreasing the cough transmission ratio. A lax vagina exacerbates this situation. If all structures are intact, then force "g" is exerted mainly at "BN", bladder neck. If the vagina is lax, there will be funnelling, so that "g" also stretches part of the suburethral vagina providing a larger counter force to PCM, than in the normal patient. This delays urethral closure even further, increases the area "S", FIG20 over which the PUSM striated muscle force is exerted, therefore decreasing the cough transmission ratio. This concept may be further developed to explain nocturia and nocturnal enuresis. Overnight, as "B" increases in volume, the nerve endings at "BN" become stretched by the funnelling, activating the micturition reflex. With nocturnal enuresis, we postulate that congenital defects 3 and/or 5 do not allow PCM to create a drum like tension in the vagina, to support the bladder neck nerve endings, thereby preventing such activation of the micturition reflex.

In an ongoing study (unpublished data), the relationship between CTR bladder volume and urine loss on handwashing provocation is penetrated. Fifty-two patients (group 1) with a previous history of mainly urge incontinence, lost urine during the handwashing test. They were compared with a similar group of 63 women (group 2) who did not lose urine during this test. The mean cough transmission ratio CTR in group 1 was 76%, and 92% in group 2. Mean bladder volumes were 453 mls and 353 mls respectively. Using a 2 sample t test, the correlation between the lowered CTR and increased bladder volume in the two groups was found to be highly significant, $p = <.00001$. i.e., it is highly likely that the increased bladder volume was responsible for the low CTR in the patients who lost urine during the handwashing "sink test".

These results are consistant with those reported by Constantinou, that CTR decreases with increased

bladder volumes in healthy females (101).

With reference to (1), we hypothesize that the PCM muscle force, FIG 23, was unable to tighten the vagina sufficiently to prevent stimulation of the nerve endings at bladder base, or to close off the urethra sufficiently during coughing (low CTR), due to the increased inertial force created by the additional weight of urine. We consider that the results confirm the main statement of the Integral Theory (1), that stress incontinence (defective urethral closure) and urge incontinence (inability to inhibit premature activation of the micturition reflex) both derive, for different reasons, from the same an anatomical defect, vaginal laxity in the suburethral/ bladder neck region.

Force generated by the pubococcygeus muscle.
The anterior portion of pubococcygeus muscle(PCM)FIG23 generates a constant force for a given stimulus, (100). Force = M x a , where M= mass and a = acceleration. If M increases (higher urine volume), 'a' decreases, as does the terminal velocity of the contracting muscle. In group 1, "S", FIG20, is enlarged due to the inertial force of the extra urine. Thus some of the muscle force generated is required to overcome this inertia. "S" FIG 20 does not close, as X, FIG 17, may not be reached. This reduces the CTR. Using the relationship between the reduced CTR and increased urine volume reported earlier, we calculated # that the total strength of pubococcygeus muscle contraction = 6.88 Newtons, and the power = 99.2 mW.

see appendix B.

Power generated by the pubococcygeus and periurethral striated muscles.
At the level of midurethra, mean power for healthy women was 4.0 mW, and for GSI women 2.0 mW, (99). We believe that we have measured the power exerted by the pubococcygeus, and that Lose (99) has measured the power of the periurethral striated muscle. These results reinforce our concept of the urethral closure mechanism having 2 components, a powerful pubococcygeus muscle contraction component (generating 99 mW), and a much weaker periurethral striated muscle contraction (generating 4 mW).

CONCLUDING COMMENTS

Though several examples of how various dynamic pressure transmission ratios may reflect specific morphological defects have been presented, it must be remembered that the mechanisms of closure are complexly interlinked, and most probably, chaotically determined, much in the same way as with "detrusor instability". Therefore a specific pattern may not necessarily be registered on one occasion, or repeatable on another.

Correspondence:
P.E. PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-4743766

IN
Lik
onc
tiss
ela
cha
str
lax
of
i)

2)

3)

ORIGINAL ARTICLE

PART III: SURGICAL PRINCIPLES DERIVING FROM THE THEORY

FOREWORD

The following section is not meant, in any way, to be a definitive handbook of urogynaecological surgery. Rather, the aim is to present our interpretation of the surgical principles derived from the Integral Theory. In the process of applying the theory to the management of female incontinence, the surgical principles described herein, and even the theory itself have been challenged, refined and modified. Most of the statements introduced are based on a significant clinical experience based over several years, encompassing close to 1000 patients. In the patient not previously operated upon, defects no 3 & 5, pubourethral ligament (PUL) and collagenous insertion ("connective tissue glue") of vagina to the under-surface of pubococcygeus muscle are considered to be the most serious defects, as they also invalidate the urethral closure mechanism, and appear to have a role in the causation of faecal incontinence too. However, we also emphasize the role of a lax posterior fornix as concerns causation of high residual urine, pelvic pain, and also, urinary incontinence.

ABSTRACT

The impact of surgery on the six structural defects according to the initial anatomical classification (p14), is analysed with reference to the 3 main functions of vagina and its supporting ligaments: as an elastic membrane connecting the urethral and bladder neck closure mechanisms, FIG3; as a transmitter of pelvic muscle contraction, FIG17; as a structural support for the nerve endings at bladder base, FIG 13. Future problems to be solved include how to more accurately diagnose a particular anatomical defect, precise pre-operative assessment of vaginal strength and elasticity, and how surgical methodology must take into account the long-term effects of ageing and scarring on connective tissue.

INTRODUCTION

Like any other organ the vagina cannot be re-created once it has been surgically destroyed. As living tissue, it is subject to age changes such as loss of elasticity, loss of structural strength, and to hormonal changes in pregnancy. As a birth canal, it may be structurally damaged, resulting in herniations and laxity. All these factors impact on the three functions of vagina and its supporting ligaments:

1) as an elastic membrane, zce, FIG 3 connecting the urethral and bladder neck closure mechanisms, allowing them to function independently.
2) as a transmitter of pelvic muscle contraction for opening and closure, FIGS 2 & 3;
3) as a structural supporting membrane for the nerve endings at bladder base, preventing their premature activation, FIG 13.

These three properties have the potential to oppose each other. The problem is solved in the living patient by active "fine-tuning" of the structural components of vagina by slow twitch striated muscle, and nervous control of smooth muscle.

REASONS FOR SURGICAL FAILURE

The tissues.

We consider the increasing failure rate of incontinence surgery with time (103) as being principally a direct function of age-related changes in the vagina, due to increasing suburethral or posterior fornix laxity, or tightening of the supralevator vagina due to scarring, or even loss of collagen "glue" between pubococcygeus muscle and vagina. Difference in elasticity is dramatically illustrated by comparing

FIGS 7a and 7b, and FIGS 11a and 11b.

Tissue strength : the vagina naturally weakens with age (98). Surgical excision and stretching of the residual vagina also potentially weakens it (98). A double flap technique "double-breasting" (cf part IV), with diathermy to the superficial epithelium of the underlying layer, is a useful technique for avoiding tissue excision, repairing a herniation (cystocele, rectocele, enterocoele), and, at the same time, bolstering the strength of the vagina. Used in the definitive version of our slingplasty procedure (cf part IV), it provides great strength to the vagina underlying the urethra, and, at the same time, appears to largely prevent "visco-elastic creep".

Tissue elasticity : this is a store of energy (93) (99). If excessive vagina is excised, the remaining tissue is stretched against the restorative force inherent in the vaginal tissue. This may cause the sutures to tear out, especially if subjected to an additional force such as a coughing fit.

Visco-elastic creep: even though there may be sufficient tensioning of vagina at the time of operation, subsequent loosening may occur due to visco-elastic creep (93). Using double-breasted flap repairs may prevent "creep" and, at the same time, greatly increase the structural strength below urethra. Such and other alternative techniques based on normal function need to be developed.

Zone of critical elasticity (ZCE) (FIG 3): this must not be over-extended during bladder neck elevation or scarred during vaginal repair, repair of cystocele, etc. Any iatrogenic stretching of vagina, e.g. during bladder neck elevation operations may mechanically fix the vagina's elasticity at full extension, as per ZCE_1. At the slightest movement of the pelvic floor, F2 may stretch the vagina to point X, FIG17, rapidly neutralizing F1, so that the urethra cannot be closed. Indeed, it opens on being given the signal to close! (tethered vagina syndrome).

Circumstance.

Excessive tension on the suture lines, e.g. from postoperative vomiting, coughing fits, falls etc. and rarely, haematoma may cause failure, but infection appears to be a rare cause. Repair of one defect may concentrate the intraabdominal pressure/pelvic floor contraction on another subclinically damaged area of vagina, causing it to "blow out", much in the manner of a perished bicycle tube.

The surgeon.

Incorrect diagnosis of the causative anatomical defect. This especially holds for urge symptoms/pelvic pain, which are often caused by a posterior fornix defect. There may exist more than one anatomical defect, or even part of one, e.g. the anterior half of the suburethral vagina may be lax, whereas the posterior part may be intact.

Hysterectomy : suturing the vaginal vault from side to side, or by a purse string suture, including fixation of the uterosacral ligaments, would potentially avoid the postoperative appearance of the "posterior fornix syndrome" and the dysfunctions inherent in this syndrome.

Suburethral scarring : inappropriate scarring on the posterior surface of urethra may also "tether" the urethra preventing its closure by the periurethral striated muscles. As the periurethral muscles are situated anteriorly, they are unlikely to be affected. We consider that such a "pipe stem" urethra is restorable by dissection of the adhesions and plication of urethra with fine sutures.

Excessive vaginal tissue excision : We advise minimal excision of vaginal tissue, especially during repair of cystocele, vault prolapse, etc., as tissue, once excised, cannot be re-created. Excessive tissue excision may cause dyspareunia and the "tethered vagina syndrome". The dilemma here is that minimal tissue excision with conventional vaginal repairs can lead to subsequent operative failure from visco-elastic creep. Given that such repairs may be performed with minimal disturbance under local anaesthesia, rather than excise excessive tissue at the first operation, it may be preferable to advise the patient that a subsequent tightening may be required.

SURGICAL APPLICATIONS ACCORDING TO THE CLASSIFICATION, FIG 2.

Defect 1 suburethral vaginal laxity.

Adequate elasticity must be maintained in the vagina; the vaginal axis must not be altered during suprapubic incontinence procedures, anchoring, not elevation of urethra being the important factor.

In its pure form with an intact (PUL), suburethral laxity is curable by simple tightening of the suburethral vagina. Performed on an unselected group of patients, success rate was less than 50% (1) (p41-42). Routine excision of a fairly large wedge of anterior vaginal wall has evolved historically, in order to anchor the urethra. Such operations rely solely on the inherent structural strength of vagina to support the urethra. *Because of the requirement for elasticity in its structure, the vagina cannot on its own account provide a structural support if the (PUL) is deficient. Such support is the function of a ligament.* Therefore there should be no other expectation from a vaginal repair than to restore the urethral closure mechanism.

Improvements to vaginal repair technique incorporating a reconstruction of the pubourethral ligaments (PUL), (1 p57) have been devised.

Even with creation of the (PUL) support, inadequate excision of vagina may result in recurrence of incontinence in up to 1/3 of patients because of "visco-elastic creep". Continence may be restored in these patients by further tightening of vagina.

Incompetent urethra.

We have previously described how the function of the smooth muscle sphincters of urethra is secondary to its insertion points in the vagina. Thus a lax vagina may predispose to a widened urethra. We have demonstrated on many occasions that opening the two vaginal wall flaps during the vaginal part of the IVS operation may result in uncontrollable urinary leakage, demonstrating the importance of the urethral closure mechanism.

Vaginal repair versus bladder neck elevation. (see also above) Simply re-creating the pubo-urethral ligament cured only 50% of patients with stress incontinence (1) (p53-59). Both suburethral tightening of the vaginal hammock (1) (p41-42), and the creation of pubo-urethral ligaments are equivalently important, and need to be performed to cure most patients. Formation of an artificial pubourethral ligament by the IVS technique (cf part IV), is a very simple local anaesthetic technique which rarely fails structurally. Tightening the suburethral vagina to the precise tension necessary to restore urethral closure without complications is far more difficult(cf section IV).

Defect 2) - Tethered vagina syndrome.

Surgical stretching of vagina alters both elasticity and tissue strength (94,95). Vaginal and incontinence surgery cannot be carried out in a vacuum, without consideration for the future effects of scarring and ageing on the vaginal tissue structures. Ageing narrows the margin of elasticity for surgery due to loss of elasticity in the vagina. The importance of elasticity can be visually assessed by comparing FIG 7a (elastic)with FIG 7b. (non-elastic), and also, FIG 11a with FIG 11b. Except for FIG 7a, there is very little movement in the vagina in the region of the pubourethral ligament, point A.

We have seen recurrence of incontinence 15 or 20 years after successful incontinence surgery. We attribute this to age-related changes in the connective tissue of the vagina, particularly matrix, collagen and elastin components. Restoration of elasticity by I-plasty, a type of Z-plasty, has been used successfully by us (1) (p63-67). *Failure of this operation will occur if there is a net deficit of vaginal tissue in the anterior vaginal wall.* We have cured 12/16 largely failed I-plasty patients (68) with application of a free graft in the "zee", thereby restoring elasticity in the bladder neck area of vagina.

Defects 3 & 5) - pubourethral ligament (PUL)/ defective insertion of vagina into pubococcygeus muscle.

These are the most serious defects as they invalidate the urethral closure mechanism. Point "A", FIGS 7a, 7b, performs its fulcrum function far below the

bladder neck. The Intravaginal Slingplasty (IVS) (cf part IV) procedure works very well with the creation of an artificial ligament directly behind the pubic symphysis, (1) (p56). Zacharin, (109) has developed a successful operation based on inserting a ribbon of rectus sheath in the position of the pubourethral ligament.

It is important to emphasize that operations that anchor the vagina in the region of bladder neck potentially inhibit extension of that part of ZCE between PUL and bladder neck, constituting approximately 50% of the zone of critical elasticity (ZCE). It is not surprising that postoperative urinary retention and difficulties with bladder emptying occur so frequently with such operations.

Our intravaginal slingplasty operation (IVS), often performed without its vaginal component, has cured also young females of symptoms such as urge incontinence, nocturnal enuresis, faecal incontinence, difficulty in evacuating the rectum, symptoms present since childhood. This has lead us to believe that defects 3 & 5 may also occur as congenital defects possibly causing nocturnal enuresis, and that the pubourethral ligament (PUL) also has an important role in ano-rectal opening and closure.

Defect 4) - posterior fornix.

The process of bladder neck opening requires coordinated simultaneous contraction of the rectum and vagina, best seen in FIG 12b, so as to enable the bladder neck to be pulled open. There must be no laxity between anterior wall of rectum and posterior wall of vagina, i.e. a high rectocele, if present, also needs to be corrected, along with any enterocoele, or laxity in the uterosacral ligaments. Careful comparison between FIGS 12a and 12b demonstrates that the fulcrum for angulation of the levator plate is actually the coccyx itself, which also angulates downwards. This indicates that LMA pulls against the whole length of the uterosacral ligament (USL). *This implies pre-existing laxity of the USL between rectum and coccyx may not be correctible by a posterior fornix repair in all cases*, something consistent with our clinical experience (cf part IV). It is possible to re-create the USL using the special tunneller to insert special removable tapes (unpublished data).

Hysterectomy and residual urine - transverse suturing of the vaginal vault (1) (p71), may cause incomplete bladder emptying, and other aspects of the posterior fornix syndrome. Suturing the vaginal vault longitudinally, or with a purse string suture provides a stronger anatomical support for the vaginal vault.

In a study of 163 patients presenting with urinary incontinence, 59 gave a history of having had a prior hysterectomy. A highly significant association was noted between a prior history of hysterectomy with high residual urine* ($p = 0.0042$); also between high residual urine and "abnormal bladder neck opening" symptoms ($p = 0.0003$) (unpublished observations). The results confirm that hysterectomy may cause abnormalities in bladder neck opening, and that high residual urine may derive from abnormal bladder neck opening. Both may be related to laxity in the uterosacral ligaments.

* >50 mls.

Congenital posterior fornix defect. We have seen lax and separated uterosacral ligaments causing stress and urge incontinence in nulliparous females. Often the symptoms are worse prior to and during periods. This we attribute to the action of hormones and prostaglandins on the cardinal and uterosacral ligaments (91).

Conclusions and future problems to be solved.

Which defect? We use our structured questionnaire, Appendix A, and characteristic clinical, radiological and urodynamic criteria as described to diagnose defects 1-6. *A particular diagnostic criterion can never be infallible, because of the modifying impact of other structures, some of which have been detailed.*

Quality of the tissues? Pre-operative use of a more sophisticated elastometer than in FIG 19b, should give vital information about the tethered vagina syndrome, and vaginal elasticity. Extensive studies will be necessary to correlate vaginal elasticity with tissue strength, and then to relate this data with surgical outcome. Because we suspect that the tissue strength may vary in different parts of the anterior vaginal wall, it may be necessary

to map more than one part of the vagina if adequate pre-operative guidance is to be sought with such techniques. Certainly these techniques would be more critical in the patient with aged tissues, but it must be remembered that adequate elasticity in a younger patient may be able hide a multitude of surgical sins today (e.g. excessive vaginal excision or elevation), but not necessarily tomorrow, when the tissues lose their elasticity.

Which operation? Will there ever be one single, universal, easily reproducible operation? Unfortunately, given the classification, no. A good working knowledge of the Integral Theory may assist in the application of the various surgical methods outlined in part IV. An intuitive awareness of tissue elasticity, and how to interpret the various diagnostic techniques outlined will be helpful. Surgical methodology must take into account the long-term effects of tissue excision, scarring, and ageing on connective tissue, as these factors potentially alter the vaginal tension. Section IV describes some of the techniques which are possible by applying the theory. *We cannot advise one set operation.* Presently each surgeon has to adjust his/her techniques as best as possible to the principles here described, to the condition of the individual patient's tissues, and last but not least, to his /her surgical skills.

Conservation of vaginal tissue. We recommend minimal excision of vaginal tissue. The operations listed in part IV are so minimally invasive, that a second procedure to adjust the vaginal tension if it is too loose is now very much a viable option, and preferable to the large tracts of vagina previously excised.

CORRESPONDENCE

P.E. PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCES for PART I

(1) Petros PE and Ulmsten U. An Integral Theory of Female Urinary Incontinence. Acta Scand O&G. (1990), Supplementum No 153. Vol 69:1-79.

(2) Jeffcoate TNA and Roberts H. Observations on stress incontinence of urine. J Obst. Gynaecol. Brit. Emp. (1952). 721-738.

(3) Bailey KV. Clinical investigation into uterine prolapse with stress incontinence: treatment by modified Manchester colporaphy. Journal of Obstetrics & Gynaecology of the British Emp. Part II, (1956), 63:663-676.

(4) Green TH. Development of a plan for the diagnosis and treatment of urinary stress incontinence. American J Obstet Gynecol. (1962), 83:632-638.

(5) Lapides, J, Ajemian EP, Stewart BH, et al. Physiopathology of stress incontinence. Surg. Gynecol. and Obstet. (1960), 3:224-231.

(6) Hodgkinson CP. Recurrent stress urinary incontinence. 1978, American J Obstet. Gynecol. (1978). 132:844-60.

(7) Hutch J A. A new theory of the anatomy of the internal urinary sphincter and the physiology of micturition. V The base plate and stress incontinence. American Journal of Obstets & Gynecol. (1966). 96-182.

(8) Olesen KP. Bladder base insufficiency. Urol Int. (1975), 30:46-53.

(9) Krantz KE. Anatomy of the urethra and anterior vaginal wall. American J. Obstet Gynecol. (1950), 62:374-386.

(10) Zacharin RF. The suspensory mechanism of the female urethra. Journal Anat. (1963). 97:423-427.

(11) Richardson AC, Edmonds PB and Williams NL. Treatment of stress incontinence due to a paravaginal fascial defect. Obst. Gynecol. (1980), 57,3:357-362.

(12) Baden WF and Walker TA. Urinary stress incontinence: Evolution of paravaginal repair. The Female Patient. (1987), 89-105.

(13) Summitt RL Jr, Bent AE and Ostergard DR. The pathophysiology of genuine stress incontinence. Int Urogynecol J. (1990), 1:12-18.

(14) Enhorning G. Simultaneous recording of intravesical and intraurethral pressure. Acta Chir. Scand. (1967), 30:309-317.

(15) Constantinou C and Govan H. Contribution and timing of transmitted and generated pressure components in the female urethra. Female Incontinence, (1981), Alan R Liss New York, 113-120.

(16) Greenwald SW, Thurbury JR, and Dunn LJ. Cystourethrography as an aid in stress incontinence. Obstet. Gynecol. (1967), 29:324-327.

(17) Kelly HK and Dumm W. Urinary incontinence in women without manifest injury to the bladder. Surgery, Gynecology and Obstetric 1914: 18:444-450.

(18) International Continence Society. (Abrams P. Blaivas J. Stanton S and Andersen J). Standardisation of Terminology of Lower Urinary Tract Function. Scand J. Urol Nephrol. (1988), Suppl. 114.

(19) Bates CP, Whiteside BM and Turner-Warwick R. Synchronous cine/pressure/flow/cystourethrography with special reference to stress and urge incontinence. Br. J. Urology (1970). 42, 714-723.

(20) Guyon S. Note Sur La Sensibilite De La Vessee A L'etat Normal Et Pathologique. (1887) Annals Des Maladies Des Organes Genito-urinaires.

(21) Barrington FJ. The relation of the hind-brain to micturition. Brain, (1921), 44:23-53.

(22) Fernsides EG. The innervation of the bladder and urethra brain 40, (1918), 149-186.

(23) Rose DK. Determination of bladder pressure with the cystometer. JAMA (1927) 88, 3:151-157.

(24) Parker MM and DK Rose. Inhibition of the bladder. Arch. Surg. 34 (1937) 828-838.

(25) Denny-Brown D and Robertson GE. On the physiology of micturition. Brain. 56, 149-190 (1933).

(26) Rehfisch (1897) as quoted by Denny-Brown (1933).

(27) Adler - as quoted by Denny-Brown (1933).

(28) Le Gros Clarke F. (1883) as quoted by Denny-Brown (1933).

(29) Meuller LR. (1931) quoted by Denny-Brown (1933).

(30) Lapides J, Ajemian EP, Stewart BH, et al. Physiopathology of stress incontinence. Surg.

Gynecol. and Obstet. (1960), 3:224-231.

(31) Hodgkinson CP. Recurrent stress urinary incontinence. American Journal Obstets & Gynecol, (1978), 132:844-860.

(32) Youssef AF. Investigarion of Sphincter Incontinence of Urine. Charles F. Thomas Springfield Illinois. (1960) 329-369.

(33) Ingelman-Sundberg A. Urinary incontinence in women excluding fistulas. Acta Obstet. Gynaecol. Scand. (1952), 31: 266-291.

(34) Stanton SL. Cardozo L. Williams J. Ritchie D. Allan V. (1978). Clinical and Urodynamic Factors of Failed Incontinence Surgery in the Female. Obstet. Gynecol. 51:515-520 (1978).

(35) Stanton SL. Colposuspension, in Surgery of female Incontinence, EDS Stanton SL and Tanagho EA, Springer - Verlag, Berlin (1986), pp 95-103.

(36) Cardozo LD and Stanton SL. Genuine stress incontinence and detrusor instability - a review of 200 patients. Brit Journ Obstets & Gynaecol 87:184, 1980.)

(37) Bent AE. Current Genuine Stress Incontinence & Detrusor Instability International Urogynecological Journ. (1990) 1:128-131

(38) Milani R, Scilambrino S, Quadri G, Algeri M. et al. Marshall Marchetti Transprocedure and Burch Colposuspension. In The Surgical Treatment Of Mild Urinary Incontinence. Brit Journ Obstets Gynaecol. (1985); 92:1050-1053.

(39) Beck RP. Arnus CHD and King C. Results In Testing 210 Patients With Detrusor Overactivity Incontinence Of Urine. American Journ Obstets. Gynecol. (1976). 125:593-596

(40) McGuire EJ and Sevastano JA. Stress Incontinence & Detrusor Instability/Urge Incontinence. Neurourol. Urodynamics. (1985);4:313-316.

(41) Meyhoff HH et al. Incontinence surgery in females with motor urge incontinence, Proc. Int. Cont. Soc. 10:109-112 (1980).

(42) Torrens MJ. A critique of urodynamics, in Urodynamics, Eds Mundy AR, Stephenson TP, Wein AJ, Churchill Livingstone, London 1984, 62-68.

(43) Cantor TJ and Bates CP. A comparative study of symptoms and objective urodynamic findings in 214 incontinent women. Br J Obstet Gynaecol. (1980) 87:889-892.

(44) Sand PK, Hill RC and Ostegard R. Incontinence History As A Predictor Of Detrusor Instability. Obstet. Gynecol. 88;71:257-259.

(45) Webster GD, Cihelnik SA and Stone AR. Female urinary incontinence; the incidence identification and characterists of detrusor instability. Neurourol. Urodyn 1984. 3:235-242.

(46) Abrams PH. Stanton SL. Idiopathic Bladder Instability Treated By Biofeedback. Brit Journ Urol. 1978;50:521.

(47) Ostergard DR. Office Evaluation Of The Incontinent Female In: Ostergard DR Editor Symposium On Gynaecological Urology 1984. New York:Nossau County Medical Center, 1984; P 1-50.

(48) Wein AJ. The pitfalls of urodynamics in Urodynamics (1984) Editors Mundy AR. Stephenson TP & Wein AJ. 150-161.

(49) ICS First Report. Bates P, Bradley WE, Glen E. et al. First Report On The Standardisation Of Terminology Of Lower Urinary Tract Function. Brit Journ of Urology (1976). 48:39-42

(50) Susset JG. Urodynamics Society Presidential Address: Urodynamics - A Step Toward Experimental Urology. Neurourology & Urodynamics 4:157-160 (1985).

(51) Petros PE and Ulmsten U. Urge incontinence history is an accurate predictor of urge incontinence Acta Obst Gynaecol Scand (1992); 71:537-539.

(52) Ulmsten U, Asmussen M and Lindstrom K. A new technique for simultaneous uethrocystometry and measurements of the urethral pressure profile. Urol Int. 32:88, (1977).

(53) Tanagho EA. The anatomy and physiology of micturition, Clinics in Obstetrics and Gynaecology. 5:1, 3-25, 1978.

(54) Petros PE and Ulmsten U Bladder instability in women: a premature activation of the micturition reflex. Neurourol. and Urodynamics -12 : 235-239 (1993).

(55) Barrow J. Theories Of Everything. The Quest For Ultimate Explanations. Oxford University Press. Oxford (1991) 11

(56) Davies SP. (1992) Simon & Schuster. London. The Mind Of God. 136.

(57) Feneley RCL and Harrison SCW. Urinary conti-

nence and micturition. Colpoproctology and the Pelvic Floor. (1992), Eds Henry MM and Swash M, Butterworth Heinemann 2nd Ed: 98-111.

(58) Aranda B & Letzt-Ribink P. Effect of voluntary attention on urethral pressure. Neurourol & Urodynam. (1991), 10:571-578.

(59) Popper KR. A Survey of some fundamental problems. On the problem of a theory of scientific method. Theories. Falsifiability. The problem of the empirical basis. Degrees of testibility. Simplicity. The Logic of Scientific Discovery. (1980), Unwin, Hyman, London. 27-146.

(60) Tanagho EA. Colpocystourethropexy, the way we do it. Journal of Urology, (1976), 116:751.

(61) De Lancey J. Correlative Study of Paraurethral Anatomy. Obstet. Gynecol. (1986), 68:91-97.

(62) Huisman AB. Aspects on the anatomy of the female urethra with special relation to urinary continence. Clinics in Obstets. and Gynecol. (1983), Karger Basel, 10:1-31.

(63) Gosling J. Structure of the lower urinary tract and pelvic floor, in clinics in Obstet. and Gynaecol. 12, 2:285-295. WB Saunders CO, London, (1985).

(64) Kennedy WT. Urinary incontinen ce relieved by restoration and maintenance of the normal position of urethra, Amer. J. Obstets. and Gynecol. 41, 16-28, (1948).

(65) Turner-Warwick R. Observations of the function and dysfunction of the sphincter and detrusor mechanisms. Urol. Clin. of North America, (1979), 6,1:13-30.

(66) Courtney H, Anatomy of the pelvic diaphragm and ano-rectal musculature as related tp sphincter preservation in ano-rectal surgery, Amer. J. Surgery, 79:155-173 (1950).

(67) Shafik A. A new concept of the anatomy of the anal sphincter mechanism and the physiology of the defaecation. II Anatomy of the levator ani muscle with special reference to puho rectalis. Investigative Urol. (1975), Vol 13, 3:175-182.

(68) Petros P and Ulmsten U. The free graft procedure for cure of the tethered vagina syndrome - this issue.

(69) Hastwell GB. Psychogenic pelvic pain or the Occult Prolapse Syndrome. Medical Journal of Australia. (1986), 144:405-407.

(70) Swash M, Henry MM, and Snooks SJ. Unifying concept of pelvic floor disorders and incontinence. Journal of the Royal Society of Medicine, (1985), 78:906-911.

(71) Keele CA and Neil E. The autonomic nervous system. Samson Wright's Physiology. (1971), 12th Ed, Eds Keele CA and Neil E. Oxford Uni Press, London. 383-396.

(72) Creed K. Functional diversity of smooth muscle. British Med. Bulletin, (1979), 3:243-247

(73) Griffiths DJ. Assessment of detrusor contraction strength or

(74) Constantinou CE. Contraction strength variance during pressure/ flow studies. Neurourol. and Urodynamics, (1991), 10:47-52.

(75) Groen J, Bosch R, and van Mastright R. Neurourol. and Urodynamics, (1991). No 4, Vol 10:332-333.

(76) Petros PE and Ulmsten U, tests for detrusor instability in women measure the urethral resistance created mainly by pelvic floor contraction as a reaction to premature activation of the micturition reflex, Acta Obstet Gynecol Scand (in press) 1993.

(76a) Petros PE Doctorate Thesis : Detrusor Instability _ a Critical Analysis, University of Uppsala, Sweden 1993.

(77) Blaivas JG, Sinha PH, Zayed AAll and Labib KL. Detrusor - external sphincter dyssynergia. Journal Urol. (1981), 125: 542-544.

(78) Blaivas JG, Labib KB, Bauer SB. and Retik AB. A new approach to electromyography of the external anal sphincter Journal Urol. (1981), 117: 773-777.

(79) Aranda B and Letzt-Ribinik P. Effect of voluntary attention on urethral pressure. Neurourol. and Urod. (1991), 10:571-578.

(80) Paramore RH. Some further considerations on the supports of the female pelvic viscera, in which the intraabdominal pressure is still further defined. Journal of Obst and Gynaec. Br, Empire, (1908),14: 172-187.

(81) Sturmdorf A. Gynoplastic Technology. Philadelphia: Davis, (1919), 109-114.

(82) Power RMII. Embryological development of

the levator ani muscle Amer. J Obstet. and Gynecol. 55;3:367-380, (1948).

(83) Francis WJA. Disturbance of bladder function in relation to pregnancy. Journal Obstet Gynecol. British Empire. (1960), 67:353-366.

(84) Cutner A, Cardozo LD and Benness CJ. Assessment of urinary symptoms in the second half of pregnancy. International Urogynecol. Jounral, (1992), 3:30-32.

(85) Ulmsten U. & Ueland K. The forces of labour. Clinical Obstets & Gynaecol (1983) 26:1-108.

(86) Nemir A and Middleton R. Stress incontinence in young nulliparous women. Amer. J. Obstet. Gynecol. (1954) 68: 1166-1168.

(87) Johnstone TB, Whillis J. Introductory myology. Gray's Anatomy 31st Edition. (1954), Eds. Longmans, Green & Co, London, 534-538.

(88) Goff BH. Secondary reconstruction of damaged pelvic floor, practical consideration of the damaged pelvic floor with the technique for its secondary reconstruction. Surgery Obstets. & Gynecol. (1928), 46:855-866.

(89) Hukins WL and Aspden RM. Composition and properties of connective tissues, Trends in biochemical sciences. (1985) 7,10: 260-264.

(90) Nordin M. Biomechanics of collagenous tissues, in Basic Bomechanics of the Skeletal System. (1980), Eds, Frankel VH & Nordin M., Lee & Febiger, Philadelphia. P87-110.

(91) Uldbjerg N & Ulmsten U. The Physiology Of Cervical Ripening and Cervical Dilatation and the Effect of Abortefficient Drugs, in Medical Induction of Abortion. Baillere's Clinical Obstetrics and Gynaecology, (1990), Editor M Bygdeman, Baillere's Tindall, London. 263-281.

(92) Downing J & Sherwood OD. The physiological role of relaxant in the pregnant rat - the effect of cervical collagen & glycosaminoglycans. Endocrinology. (1986), 118, 2:471-479.

(93) Thonar EJMA & Kuettner KE. Biochemical basis of age related changes in proteoglycans. Biology of Protoeglycans. (1987), Editors Wight TN & Mecham RP, Academic Press Inc. P211-246.

(94) Yamada H. Mechanical properties of urogenital organs and tissues in Strength of Biological Materials, (1970), Williams & Wilkins Co. Baltimore. Ed Evans FG. 205 218.

(95) Yamada H. Aging rate for the strength of human organs and tissues. Strength of biological materials. (1970), Williams & Wilkins Co. Baltimore. Ed Evans FG. 272-280.

(96) Peacock EE. Structure, synthesis and interaction of fibrous protein and matrix. Wound Repair. (1984), 3rd Edition, Publishers WB Saunders Co. Philadelphia. 56-101

(97) Yamauchi M, Woodley DT and Mechanic GL. Aging and cross-linking of skin collagen. Biochemical and Biophysical Research Communications. (1988), 152. 2:898-901.

(98) Bailey AJ, Ranta MH, Nicholls AC. Partridge SM and Elsden D. Isolation of alpha amino adipic acid from mature dermal collagen and elastin. Evidence for an oxidative pathway in the maturation of collagen and elastin. Biochem. & Biophysical Research Communications. (1977), 78, 4:1403-1409.

(99) Lose LG. Study of Urethral Closure Function in Healthy and Stress Incontinent Women. Neurology and Urodynamics, (1992) 11:55-89.

(100)Hill AV. The Heat of Shortening and the Dynamic Constance of Muscle Proceedings of Royal Society of London (1938) B 126: 136-195.

(101)Constantinou CE. Resting and stress urethral pressures as a clinical guide to the mechanism of continence. Clinics in Obstets & Gynecol. (1985), 12, 2:343-356.

(102)Tanagho EA and Stoller ML. Urodynamics: Uroflowmetry and female voiding patterns. Urogynecology and Urodynamics Theory and Practice, (1991), 3rd ed. Eds. Ostergard D and Bent AE. 164-170.

(103)SpencerJR, O'Connor Jr. VJ and Schaffer AJ. A Comparison of Endoscopic Suspension of the vesical neck with suprapubic vesicourethropexy for treatment of stress in urinary incontinence. Journal of Urology 1978: 137:411-415.

(104)Zacharin RF. Abdominoperineal urethral suspension in the management of recurrent stress incontinence of urine. Obstet. Gynecol. (1983), 62:644-654.

APPENDIX A

PATIENT QUESTIONNAIRE

NAME :

ADDRESS :

TELEPHONE :

DATE: _____

DATE OF BIRTH :

WEIGHT :

NO. OF VAGINAL DELIVERIES ( )

NO. OF CAESAREAN SECTIONS ( )

DESCRIBE IN YOUR OWN WORDS YOUR MAIN URINARY SYMPTOMS AND DURATION:

ALL SECTIONS : TICK APPROPRIATE SQUARE ( ). Write extra details if you wish

S.I. SYMPTOMS	YES	NO	50%or more
DO YOU LOSE URINE DURING:			
SNEEZING	( )	( )	( )
COUGHING	( )	( )	( )
EXERCISE	( )	( )	( )
LAUGHING	( )	( )	( )
(1*) WALKING	( )	( )	( )
(2*) PICKING UP OBJECTS OFF THE FLOOR	( )	( )	( )
SYMPTOMS OF DEFICIENT EMPTYING			
(3*) DO YOU FEEL THAT YOUR BLADDER DOESN'T EMPTY PROPERLY?	( )	( )	( )
(3*) DO YOU EVER HAVE DIFFICULTY STARTING OFF YOUR STREAM?	( )	( )	( )
(3*) IS IT A SLOW STREAM?	( )	( )	( )
(3*) DOES IT STOP AND START INVOLUNTARILY?	( )	( )	( )
VOLUNTARY "CUT-OFF"			
(4*) CAN YOU INTERRUPT YOUR STREAM?	( )	( )	( )
URGE SYMPTOMS:			
DO YOU EVER HAVE AN UNCONTROLLABLE DESIRE TO PASS URINE?	( )	( )	( )
IF SO, DO YOU EVER WET BEFORE REACHING A TOILET?	( )	( )	( )
DO YOU FEEL URGENCY WHILE WASHING YOUR HANDS OR SHOWERING?	( )	( )	( )
(5*) DO YOU HAVE PAIN WHILE PASSING URINE?	( )	( )	( )
(6*) IN THE MORNING DO YOU WET BEFORE REACHING THE TOILET?	( )	( )	( )
HOW MANY TIMES DURING THE NIGHT DO YOU GET UP TO PASS URINE?		write number	( )
HOW MANY TIMES DO YOU PASS URINE DURING THE DAY?		write number	( )
DID YOU WET THE BED AS A CHILD? YES / NO			

BOWEL SYMPTOMS:

(7a*) DO YOU HAVE PROBLEMS EMPTYING YOUR BOWELS? YES / NO

(7b*) DO YOU EVER SOIL YOURSELF (FAECES)? YES / NO

DO YOU HAVE ANY OTHER BOWEL PROBLEMS? (DESCRIBE)

SOCIAL INCONVENIENCE:

(8*) ARE YOU "MOIST" ALL THE TIME? YES / NO

(9*) DO YOU LEAVE PUDDLES ON THE FLOOR? YES / NO

DO YOU LOSE URINE IN BED AT NIGHT? YES / NO

DO YOU HAVE TO WEAR A PAD ON GOING OUT NEVER /SOMETIMES /ALWAYS

PREVIOUS OPERATIONS:

(10*) HAVE YOU HAD A HYSTERECTOMY OR VAGINAL REPAIR (CIRCLE WHICH)? when?____ / NO

(11*) HAVE YOU HAD PREVIOUS SURGERY FOR YOUR INCONTINENCE? when? _____ / NO

ARE YOU better OR worse SINCE? (CIRCLE WHICH)

(12*) HAVE YOU HAD AN " ANAL STRETCH" OR HAEMORRHOIDECTOMY? when ? _____ / NO

	YES	NO	50%or more
(13*) PELVIC PAIN :			
DO YOU HAVE DEEP PAIN ON INTERCOURSE?	( )	( )	( )
DO YOU HAVE A PAIN DOWN AT THE BOTTOM OF YOUR SPINE?	( )	( )	( )
DO YOU HAVE A PAIN DOWN AT THE BOTTOM OF YOUR ABDOMEN?	( )	( )	( )
DO YOU FEEL TIRED AND IRRITABLE AT THE END OF THE DAY?	( )	( )	( )

SECTION BELOW FOR OFFICE USE ONLY (CONCLUSIONS / SUGGESTED DIAGNOSIS)**

* ASTERISK DENOTES THAT A PARTICULAR SYMPTOM MAY BE FREQUENTLY FOUND WITH A PARTICULAR CONDITION

1* — low MUP with too loose or too tight SLV.

2* — if this is the only SI symptom,it is termed "paradoxical leakage", and must exclude tethered vagina syndrome in patients with previous vaginal surgery.

3* — USL, SLV, posterior vaginal wall laxity, but also after excessive bladder neck elevation .

4* — voluntary closure mechanism defective per se , but generally found in more major defects, e.g. PUL

5* — exclude UTI, chlamydia, etc.

6* — tethered vagina with previous operation, but also PUL defect with no previous operation.

7a* — may be due to defective PUL and /or rectocoele.

7b* — defective PUL and /or anal mucosal prolapse (descending perineal syndrome).

8* — low MUP / usually with lax suburethral vagina or tethered vagina syndrome.

9* — denotes defective PUL, but may be also due to defective CT "glue" between vagina/PCM.

10* — must exclude USL defect.

11* — must exclude tethered vagina syndrome in patients without previous hysterectomy.

12* — possible torn external anal sphincter.

13* — USL defect.

APPENDIX B

Force generated by the pubococcygeus muscle. FIG 23.

The pubococcygeus muscle generates a constant force (F1) for a given stimulus (98). Force = Mxa where M= mass and a = acceleration. If M increases (higher urine volume), 'a' decreases, as does the terminal velocity of the contracting muscle. If the vagina is loose, some of the muscle force generated may not be transmitted, as X, may not be reached.

Work generated by pubococcygeus muscle.

PCM, FIG 23, must overcome the inertial force of gravity"g" acting on the volume of urine. Calculating from our data, the mean force generated by our patients was 92/16 x .109 x 9.8 Newtons = 6.14 Newtons, where mass = 109 gms., g = 9.8, and 92/16 represents the inverse of the fractional decrease in CTR. Based on the data from the stress extension curve in FIG 17 (93), the vagina requires to be elongated 80% so as to be able to transmit a contraction without further extension. i.e. a force of 20 gm/sq mm is required. Expressed as Newtons (Kg/sq M): .02 x 100 x 100 = 200 Newtons/sq M. Taking the vagina to be a cylinder, 12 cm long, and with a radius of 2 cm, total area of vagina is $2\pi r$ x 12 = 150.8 sq cm. Taking the area of anterior vagina up to the bladder neck as constituting 1/4 of the total vagina, then the area of vagina effectively being tensioned by the forward movement of pubococcygeus muscle is 150.8 /4 = 37.7 sq cm. Therefore the approximate force needed to stretch the vagina to the point where it has no more elasticity is 200 x .0037 = .74 Newtons. Therefore the total strength of the muscle contraction is 6.14 + .74 = 6.88 Newtons#. If it is accepted that the muscle contracts 1.5 cm forwards. The work is therefore FxDist. = .0992 Joules.

Power generated by the pubococcygeus muscle.

If a cough occurs over 1 second, then the power generated averages out at .0992 W or 99.2 mW. An assumption was made that the tension curve of the rabbit vagina was similar to the human. This is so for rabbit ureter, bladder and trigone, Yamada (93,94).

According to Zacharin, (103) the distance between the insertion point of pubourethral ligament and the symphysis pubis is 1.5 cm in the cadaver. In the live patient (FIG 7a), The distance A-PS is clearly longer than 1.5 cm. so that the power generated would be higher.

we have made several assumptions: therefore this result is an approximation only.

PART IV: SURGICAL APPLICATIONS OF THE THEORY - DEVELOPMENT OF THE INTRAVAGINAL SLING PLASTY (IVS) PROCEDURE

Key words: urinary incontinence; female incontinence surgery;

Authors: PE PAPA PETROS,MB BS Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala Sweden

I. An anatomical basis for success and failure of female incontinence surgery.
II. The development of the intravaginal slingplasty procedure: IVS II - (with bilateral "tucks").
III. Further development of the intravaginal slingplasty procedure: IVS III - (with midline "tuck").
IV. Further development of the intravaginal slingplasty procedure: IVS IV - (with "double-breasted" unattached vaginal flap repair and "free" vaginal tapes).
V. Further development of the intravaginal slingplasty procedure: IVS V - (with "double-breasted" unattached vaginal flap repair and permanent sling).
VI. The intravaginal slingplasty procedure: IVS VI - (further development of the "double-breasted" vaginal flap repair - attached flap).
VII. The free graft procedure for cure of the tethered vagina syndrome.
VIII. The posterior fornix syndrome: A multiple symptom complex of pelvic pain and abnormal urinary symptoms deriving from laxity in the posterior fornix of vagina.

FOREWORD

Our techniques for surgical correction of urinary incontinence are a direct application of the Integral Theory and its biomechanical derivations. Correction of 5 of the 6 causative anatomical defects is described in this section. If the anatomical defects are correctly identified, the techniques described here have been demonstrated to cure stress incontinence, bladder instability, (when the cause is premature activation of the micturition reflex), non-stress non-urge incontinence in the elderly, and "leakage all the time" from urethral incompetence.

Re-creation of the pubourethral ligament, and tightening the suburethral vagina were found to be equally important for cure of stress and urge incontinence (1). Recreation of the pubourethral ligament using the special tunneller rarely fails structurally. The instrument automatically positions the tape in the precise position of the pubourethral ligament. Formation of the artificial pubourethral ligament appears to be adequate using either Teflon or Mersilene. The development of the IVS operation in the subsequent papers is therefore largely a story of the advantages and disadvantages of various techniques for anatomical correction of suburethral vaginal laxity, how these techniques impact on the biomechanical concepts presented earlier, and how the compromised tissues impact on these techniques. As the tissues are often frail and lacking in elasticity, the operations here described do require a precise surgical technique. An intuitive understanding of vaginal, perivaginal and ligamentous tissues is essential for surgical success using our techniques, as structural strength and elasticity diminish with age, narrowing the margin for error with restorative surgery. The discipline of operating under local anaesthesia greatly enhances the surgeon's precision and intuitive sensitivity to tissues.

Operative failure using this new method is usually associated with:

a) wrong diagnosis of the causative anatomical defect;
b) tearing out of sutures
c) loosening of the vagina by "visco-elastic creep (this may partly re-tighten after 6 months)
d) scarring at bladder neck (if tissue excision extends beyond bladder neck)
e) especially in old ladies, decompensation of the tissues in the posterior part of vagina following strengthening of the anterior vagina by the Intravaginal Slingplasty operation.

The first paper in this section deals with some presently existing techniques for surgical treatment of female urinary incontinence interpreted in the light of the Integral Theory. In the subsequent papers, a serial evolution of the IVS procedure is presented. Most of the biomechanical/surgical principles introduced in part III were empirically tested/derived within these procedures. We have found that the more evolved procedures as described in papers IV V and VI work quite properly with high primary success rate. Simultaneously they fulfill the criteria for "simple office procedures", i.e. the patient is operated under local anaesthesia without postoperative catherization and early return to daily work. Ongoing randomised prospective studies will hopefully identify which version is to be recommended on which specific occasion.

Finally, it is obvious that this new method centres around the vagina, both theoretically, and surgically. Though we are both gynaecologically, trained. **we both believe, unequivocally, that these new techniques should be practised equally by INTERESTED urologists and gynaecologists, both of whom will need to adapt to the new concepts of vaginal conservation.** We do not consider that the actual surgical techniques are difficult to learn. The important thing will be understanding the theory and biomechanics so that proper diagnosis and surgical correction may be made. *Other than correct and precise re-creation of the ligaments**, the fine points of technique will necessarily depend on the individual surgeon. We suggest that whatever technique is used, the patient must be told that, because of the decompensated nature of the vaginal tissues, failure may occur in up to 20%, so that a subsequent adjustment to the vaginal tension may be necessary.

* we emphasize the importance of using the special tunneller here.

ORIGINAL ARTICLE

AN ANATOMICAL BASIS FOR SUCCESS AND FAILURE OF FEMALE INCONTINENCE SURGERY

PE PAPA PETROS, MB BS Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia
and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Sweden

ABSTRACT

The reasons why surgical procedures for cure of stress incontinence succeed and fail are outlined, with special reference to the various anatomical defects in the vagina and its supporting ligaments which may cause defective bladder neck opening and closure.

INTRODUCTION

This analysis is based on the consideration that it is the tensioned vagina which opens and closes the bladder neck (1), and that laxity in the vagina or its supporting ligaments may cause symptoms of stress incontinence, urge incontinence or inability to initiate micturition.

In the normal patient

"Resting closed position" (FIG 1). The vagina is suspended anteriorly by the pubourethral ligament (PUL)(2), superiorly by the arcus tendinaeus fasciae pelvis, (3), and posteriorly by the uterosacral ligament (USL) (1). The slow twitch muscle fibres tension the vagina against its supporting ligaments, like the membrane of a drum, pubococcygeus muscle (PCM) pulling the vagina anteriorly, levator plate (LP) posteriorly, and the longitudinal muscle of the anus (LMA) inferiorly.

"Active closed". Fast twitch contraction forward of (PCM) pulls the two ends of the ascending vagina (Figure 1) tightly around the urethra, closing it off and immobilizing it while (LP) and (LMA) pull the bladder down and back like an elastic balloon, kinking off and closing off the urethra as you would close off a hose. At the same time, the stretched vagina supports the nerve endings (N) at the bladder base. By supporting these nerve endings it prevents the premature activation of the micturition reflex. For these opposite muscle movements to occur, there needs to be sufficient elasticity in the bladder neck area. This is called the "zone of critical elasticity" (1). Loss of elasticity here may cause the forward movement of vagina to be cancelled out, leaving the bladder neck in the incontinent "open position", (Figure 1).

"Open position".

With bladder neck opening, exactly the same muscle movements occur as in bladder neck closure, except that (PCM) relaxes during opening. As part of the micturition reflex, (PCM) relaxes. This allows (LP) and (LMA) to uninhibitedly pull at (X), opening the bladder base, creating a "funnel", enlarging the urethral outlet. At the same time, this stimulates the nerve endings (N), activating and reinforcing the micturition reflex.

In the patient with bladder dusfunction

Stress/urge incontinence

may result from laxity in the vagina or its supporting ligaments. Loss of the drum like tensioning may cause defective closure (stress incontinence), or deficient inferior support for the nerve endings (N), leading to premature activation of the micturition reflex, (urge incontinence, or "bladder instability"). It is possible for voluntary contraction of the pelvic floor to reverse this reflex by tensioning the vagina, thus supporting "N" from below (1). Motor urge

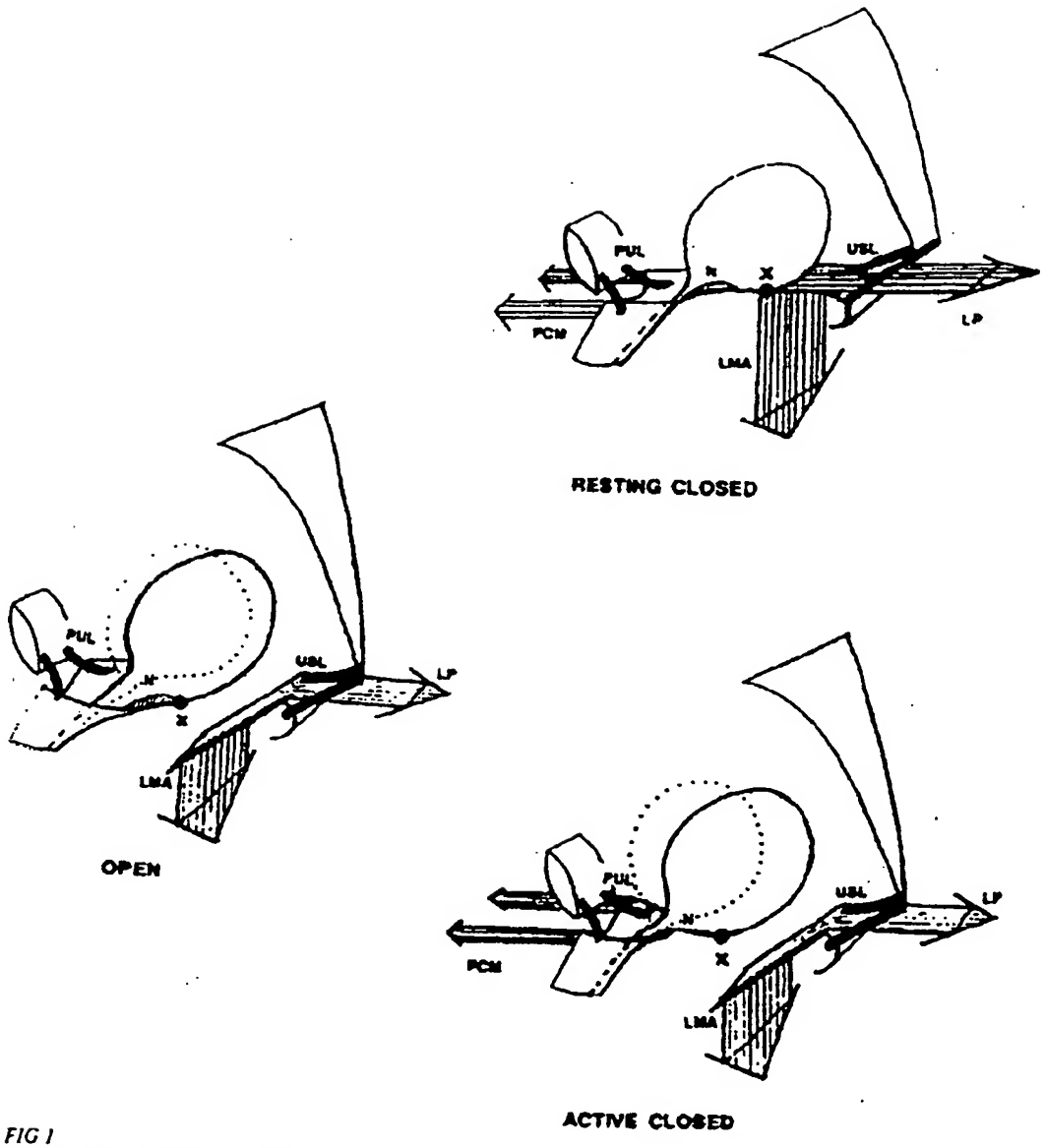


FIG 1

Bladder neck opening and closure.

This is a 3 dimensional schematic representation of the bladder and urethra lying inside the anterior vaginal wall ("hammock"). The broad arrows indicate the muscle forces exerted on the anterior vaginal wall, tensioning it like the membrane of a drum.

PUL = pubourethral ligament, USL = uterosacral ligament, "N" = specialized nerve endings at the bladder base, "X" = vesicovaginal ligament, PCM = pubococcygeus muscle, LP = levator plate, LMA = longitudinal muscle of the anus. The broken lines indicate the resting position of the bladder.

The objective of every operation is to convert "open" (incontinence during effort) to "active closed" (continence during effort).

incontinence is considered to be an end-point of urge incontinence, whereby patients cannot reverse the micturition reflex by upward tension from the voluntary closure mechanism (1).

Defective opening

may also result from a lax supralevator vagina. It may be expressed as difficulty in initiating micturition, stopping and starting, low flow, and high residual urine, due to inability to sufficiently stimulate "N" (1). Laxity in the uterosacral ligaments dissipates the contraction of LMA, FIG1, preventing proper funnelling into the "open" position, and therefore not sufficiently activating the nerve endings"N" so as to initiate micturition. Residual urine may thus be simply an end-point of this inability to open the bladder.

THE ANATOMY OF SURGICAL SUCCESS AND FAILURE ACCORDING TO (1).

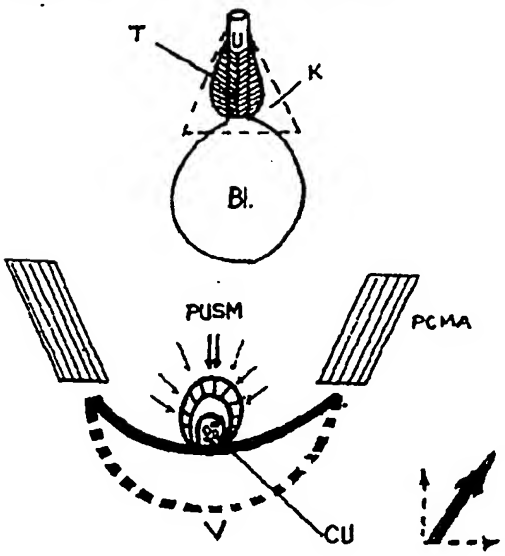


FIG 2
Vaginal repair.
Upper diagram: the interrupted lines correspond to the wedge excision (K), Kelly Repair, of the anterior wall of vagina. The vaginal "tuck" procedure is indicated by the cross-hatched area "(T)". Bl = bladder; U = urethra. The lower diagram represents a cross-section taken at the level of the mid-urethra. (PCMA) = pubococcygeus muscle (CU) = cresta urethralis, (PUSM) = periurethral striated muscle. The vector forces from (PCMA) are shown in the bottom right hand corner.

VAGINAL REPAIR

Normal urethral closure: (FIG 2) Contraction of the anterior portion of pubococcygeus muscle (PCMA) pulls the cresta urethralis (CU) towards the periurethral striated muscle (PUSM) by tensioning the vagina (V), at the same time anchoring the insertion of the periurethral striated muscle (PUSM). (PUSM) contraction seals off the urethra.

Vaginal laxity: This will not allow the pubococcygeus muscle to create the tympanitic membrane to close off the urethra and to allow the bladder neck closure mechanism to operate (FIGS 1, 2). What a vaginal repair does, is take out some of this lax tissue, so that the muscles acting on the vagina can now stretch it sufficiently to close off the urethra (Figure 2 interrupted lines). Therefore, a vaginal repair (Kelly procedure (4)) restores this component of the urethral closure mechanism. It follows that there should not be other expectations of a vaginal repair. The same effect can be achieved by doing a midline incision with a scalpel stopping just short of the bladder neck, dissecting laterally and excising a much smaller segment of vagina("T", FIG2), and suturing it with horizontal mattress sutures. This procedure is easily performed under local anaesthesia as an office operation. It is possible to prevent postoperative retention in vaginal repair operations by stopping the suburethral incision one centimetre short of the bladder neck. The vaginal repair is an important part of the surgical armamentarium, as it restores the urethral closure mechanism (1).

Failure of vaginal repair operations. There may be other anatomical defects, e.g. USL, PUL defects etc., FIG 1. The vaginal repair itself may cause failure. Insufficient tissue may be excised. Alternatively, creation of a rigid scar across the bladder neck may cause the more powerful (LP) and (LMA) muscles to cancel the forward movement of PCM needed for urethral closure (FIG 1). The end result is an open instead of a closed position for bladder neck on effort. This condition has been designated as "the tethered vagina syndrome" (5).

The typical sequence is: as soon as the patient's foot hits the floor, the levator plate has to contract to keep

the intraabdominal contents in place. The forward movement of PCM necessary to close bladder neck is "tethered" by LP FIG 1, the bladder neck remains open and the patient wets all the way to the toilet.

ABDOMINAL PROCEDURES.

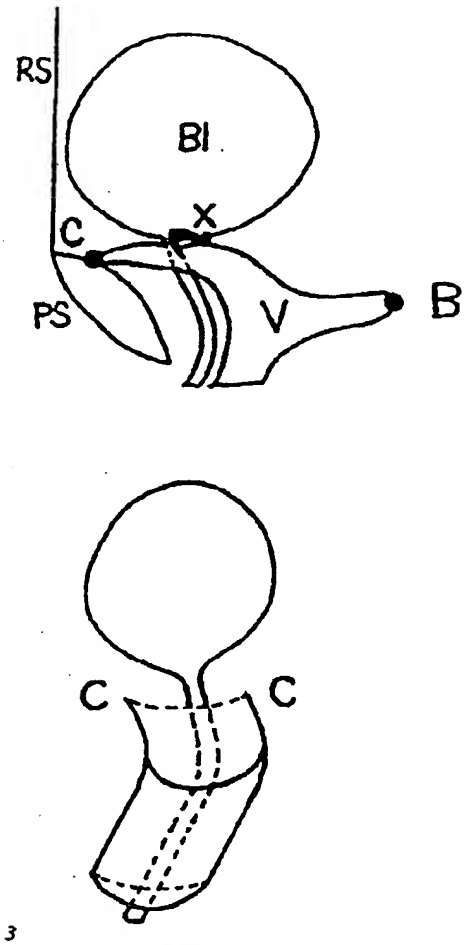


FIG 3
Colposuspension operations.
The upper diagram represents a sagittal section of the bladder and vagina in a patient who has had a colposuspension. "C" represents the bony attachment point, and "X" the vaginal attachment point. The lower diagram represents the elevated (stretched) anterior wall of vagina (V) and bladder (B1)viewed from behind, and indicates how elevation can tighten a lax vagina by elongating it. (RS) = Rectos Sheath; (B) = Posterior Fornix; (PS) = Public Symphysis.

Colposuspension operations (FIG 3) anchor the proximal urethra by elevating the vagina in the bladder neck region and attaching it directly to the periosteum of the pubic symphysis (6), Coopers Ligament, (7) using a permanently implanted nylon suture either sutured into vagina, (8), or by anchoring it in a square piece of dacron (9). Elevation tightens the suburethral vagina by elongating it and it fixes the bladder neck allowing the bladder neck closure mechanism to operate. If there is sufficient elasticity in the anterior vaginal wall to permit the opposite muscle movements to occur, (FIG 1), these operations work well. If, however, (C-X) is too tight, and the funneling necessary for bladder neck opening, (FIG 1), cannot be achieved, there may be flow defects and urinary retention, sometimes permanent (10). The elevation may also chronically stimulate "N" . Fig 1, creating new incidence of urgency in these procedures.

The potential exists for anatomical distortion in this operation. In the long term this may create severe problems, because connective tissue is not a static substance. As concerns the crossbonding of collagen fibrils, it is known that the inter and intramolecular cross-bonding increases with age (11), making the connective tissue less elastic and more brittle. Excessive stretching of old tissues during bladder neck elevation procedures is more liable to rupture the elastin component, causing them to lose much of their structural integrity, resulting in an extreme form of the "tethered vagina syndrome" (1). Operative failure may also occur years later due to age - related loss of elasticity and contraction of scar tissue, again resulting in the tethered vagina syndrome (1). Pulling the vagina upwards may elongate the uterosacral ligaments, accounting for the up to 7.6% incidence of enterocoele, (7).

Use of non-autologous materials and slings. Nylon and Dacron patches(8) (9), may irritate the tissues to form granulation tissue, discharge and of course chronic suprapubic pain (12).

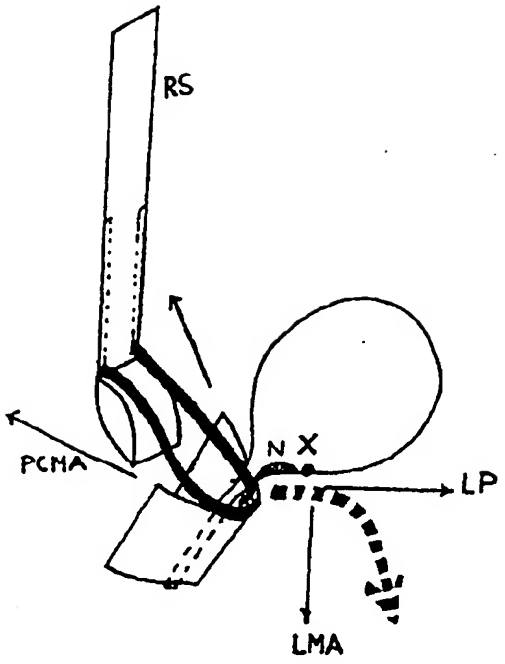


FIG 4
Sling operations.
This figure represents a 3 dimensional view of the suburethral vagina and the bladder in an Aldridge Sling operation looked at from behind. Strips of rectus sheath (RS) are configured below the urethra (dark heavy lines). The heavy interrupted arrow represents the vector forces from levator plate (LP), and longitudinal muscle of the anus (LMA). "N" = specialized nerve endings at the bladder base, "X" = vesicovaginal ligament, (PCMA) = anterior portion of pubococcygeus muscle.

Sling Operations

The Aldridge sling operation (13), is often used in cases where bladder neck elevation procedures have failed. If a sling is placed as indicated in FIG 4, the bladder neck will be forcibly restrained so that the bladder neck closure mechanism can operate. The proximal urethra is directly immobilized, preventing the activation of "N", FIG 1, and the micturition reflex, permitting cure of uninhibited detrusor contractions (14). Note how the sling provides a fulcrum allowing the (PCMA) to activate the urethral closure mechanism, and (LP) and (LMA) to activate the bladder neck closure mechanism.

However, as the bladder neck is forcibly restrained against involuntary opening, it is also forcibly stopped from funnelling, FIG 1, during micturition. Therefore, urinary retention, slow flow, and difficulty initiating micturition are common features of these operations (15). These operations require skill, judgment and luck, as subsequent muscle and scar contraction may result in transection of the urethra. Herniation may occur at the site where the fascia has been taken. Using nylon (Zoedler) (15) or dura mater (Lyodura) (15) lessens the dangers of incisional hernia found with the Aldridge operation, but increases the chances of transecting the urethra, especially in unskilled and inexperienced hands.

Summary of problems with abdominal operations: they are major procedures with the potentiality for causing haemorrhage, thrombosis, and prolonged hospitalization (10). With a Stamey and Peyrera operations there may be also suprapubic pain. Indwelling catheterization for several days is a feature as is urinary retention, flow problems, and urgency. The long term failure rate may be as high as 40% according to a comprehensive literature survey (16).

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCES

(1) Petros P and Ulmsten U. An Integral Theory of Female Urinary Incontinence. Acta Obstet et Gynecol Scand 1990; Supplementum No 153,69:7-31.
(2) Zacharin RF. The suspensory mechanism of the female urethra. J Anat 1963;97:423-427.
(3) De Lancey J. Correlative Study of Paraurethral Anatomy. Obstet. Gynecol. 1986;68:91-97.
(4) Kelly HK and Dumm W. Urinary incontinence in women without manifest injury to the bladder. Surgery, Gynecology and Obstetric 1914;18:444-450.
(5) Petros P and Ulmsten U. The tethered vagina syndrome, postsurgical incontinence and l-

plasty operation for cure. Acta Obstet et Gynecol Scand. 1990; Suppl. No 153, 69:63-67.
(6) Marshall VF, Marchetti AA and Krantz KE. The correction of stress incontinence by simple vesicourethral suspension. Surgery Gynecol. and Obstetrics 1949;88:509-518.
(7) Burch JC. Cooper's ligament urethrovesical suspension for stress incontinence. Am. Journal of Obstet. Gynecol. 1968; 100:764-772.
(8) Pereyra AJ. A simplified surgical procedure for the correction of stress incontinence in women. Western Journal of Surgery, Obstetrics and Gynecol. 1959;67:223-228.
(9) Stamey TA. Endoscopic suspension of the vesical neck for urinary incontinence in females: report on 203 consecutive patients. Annals of Surgery 1980:192:465-471.
(10) Hodgkinson CP and Stanton SL. Surgery of Female Incontinence. Eds. Stanton SL and Tanagho MLA, Springer-Verlag Berlin 1980; 66-67.
(11) Peacock EE. Wound Repair. WB Saunders Co, Phil. 3rd Ed 1984; 99-105.
(12) Richardson D A, Bent AE, Ostergard DR and Cannon D. Delayed reaction to the Dacron buttress, used in urethroplexy. Journal of Reproductive Medicine 1984;29,9:689-692.
(13) Aldridge AH. Transplantation of fascia for relief of urinary stress incontinence. Am. J. Obstet. Gynecol. 1942;44:398-411.
(14) McGuire EJ and Lytton B. Pubovaginal procedure for stress incontinence. Journal of Urology 1978;119:82-84.

ORIGINAL ARTICLE

THE DEVELOPMENT OF THE INTRAVAGINAL SLINGPLASTY PROCEDURE: IVS II - (with bilateral "tucks").

Authors:
PE PAPA PETROS*, MB BS Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden
and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT

A new local anaesthetic procedure, the intravaginal slingplasty operation performed with bilateral "tucks" was performed on 39 patients with stress incontinence, and 18 patients with urge incontinence. The operation is performed through a 1-2 cm suprapubic incision and works by creating an artificial pubourethral ligament and by tightening the suburethral vagina. The primary operation cured 64% of 39 patients with stress incontinence, and 90% of 18 patients with urge incontinence. A minor surgical adjustment to the vaginal wall tension in the failed SI group at a later date improved the 15 month success rate to 90%.

This procedure is promising in that it is minimally invasive, does not require postoperative catheterization, and allows return to work within 7-10 days.

The results emphasize the importance of the pubourethral ligament and adequate suburethral vaginal tension for adequate bladder neck closure, and the effect of bladder neck scarring in the causation of urinary incontinence. Further development is required.

INTRODUCTION

A new ambulatory surgical procedure performed in two stages was recently reported, the Intravaginal Sling Procedure (IVS I), (1). Stage 1 consisted of an adjustable sling operation. This primary procedure cured 50% of patients. Stage 2 was performed on the 50% of patients who failed to be cured by the sling operation, and consisted of tightening of the suburethral vagina by excision of leaf-shaped segments of vaginal epithelium (tucks). This improved the success rate to 82.5%. Both procedures also simultaneously cured pre-existing urge symptoms in almost all patients cured of their stress symptoms. There was no new incidence of urgency.

Experimentally, (2), the Stage 1 operation was shown to accurately create an artificial pubourethral ligament. Radiologically (1) it was shown to support the bladder neck on straining with no post operative bladder neck elevation, implying that tape insertion per se, and not elevation by the sling was responsible for return of continence.

On the basis of these results, it was decided to perform the next group of operations where possible, entirely under local anaesthesia/midazolam, and to perform the "tuck" procedure simultaneously with the insertion of the tape.

PATIENTS MATERIALS AND METHODS

Fifty-seven patients with no previous history of incontinence surgery were referred for treatment of urinary incontinence. Stress incontinence (SI) was objectively the major incontinence problem in 39 patients, whereas urge incontinence symptoms were dominant in the remaining 18 patients. Age ranged from 25 to 72 years (mean 50.5), parity, 1 to 5 (mean 2.5), and weight from 53 to 105 kg (mean 68 kg). In the first instance, all patients had an intravaginal slingplasty procedure performed, according to Fig 2. Owing to inadequate continence control, 13 patients had a further vaginal adjustment performed between 3 and 6 months after the primary operation. The adjustment aimed to either tighten the suburethral vagina (tuck), or to loosen an excessively tight bladder neck, (I-plasty) (5).

Diagnostic procedures. All patients were assessed pre operatively, and where possible postoperatively, with full history (questionnaire and interview), and physical examination, standing lateral x-ray in resting and straining positions, with a dye filled Foley catheter. Exercise pad tests were also carried out, including coughing (x10) and star (scissor) jumps (x10), with 500 mls. instilled methylene blue saline. Urine loss was quantified after each exercise by pad weighing. In addition to the above, supine filling cystometry, urethral pressure profiles, cough transmission ratios, and urodynamic flow/pressure tests were performed. Cure of SI was defined as less than 0.5 gm of urine on pad testing. In the small number of patients who, for different reasons were not objectively tested, anything other than a small occasional urine loss with coughing or sneezing was defined as a failure. Cure of urgency was defined as symptomatic disappearance of urge symptoms, and the objective cure of urge symptoms/urine loss on provocative testing.

Surgical procedure. The Intravaginal Slingplasty was performed under local anaesthesia/midazolam. No preoperative antibiotics were used. The patients were placed in the lithotomy position. At least 50 mls of 0.25 prilocaine with 1/200,000 adrenalin, was injected suprapubically into the skin, fascia of the rectus abdominis, and 30-40 mls into the vaginal mucosa and paraurethral tissue extending to behind the inferior surface of pubic bone.

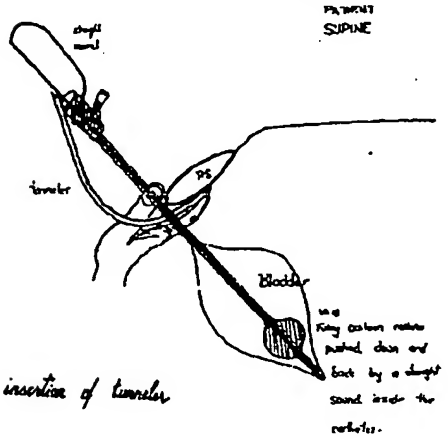


FIG 1
Insertion of tunneller.
The conical head is tightly controlled against the posterior surface of the pubic symphysis. The bladder is pushed down and away from the instrument.

After the bladder had been emptied, a straight introducer was inserted into a transurethrally inserted Foley catheter, FIG 1. A 1.5 cm incision was made in the mid-line just above the superior aspect of the pubic symphysis. Using a scalpel, two small vertical incisions were made laterally 1 cm inferior to the line of external urethral meatus, a special tunneller FIG 1, brought out over the superior surface of the bone into the skin incision, and a specially prepared 0.5 x 45 cm Mersilene tape inserted as described previously (1), (2), (6). The procedure was repeated on the contralateral side. Just prior to removal of the tunneller, the bladder was filled with 250-300 mls of saline, and a cystoscopy performed before proceeding further. Bilateral, paraurethral, leaf-shaped excisions of vaginal tissue, ("tucks"), 4-5 cm long by 0.5-1 cm wide were made (7), FIG 2.

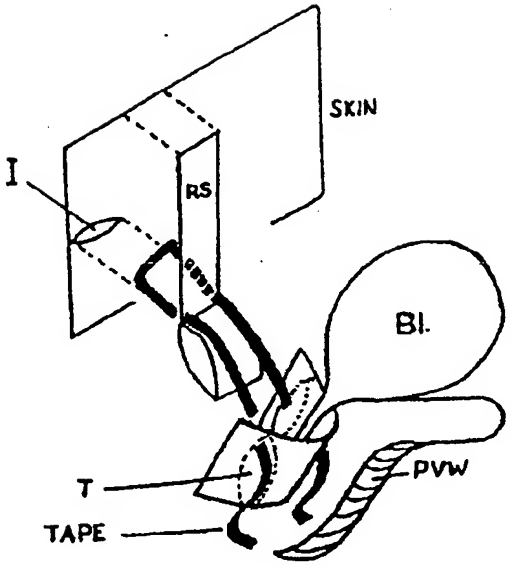


FIG 2
The intravaginal slingplasty procedure with bilateral "tucks".
T = "tuck"; I = incision in anterior abdominal wall; Bl. = bladder; RS = rectus sheath; AVW = anterior vaginal wall; PVW = posterior vaginal wall.

The 2 limbs of the inverted "U" thus descended through the sheath, behind the symphysis, and exited into the vaginal cavity where they were trimmed and left freely protruding, FIG 2. The cut edges of vagina were approximated with interrupted No 1 Dexon, and the suprapubic wound closed. Postoperative catheterization was routinely omitted in these patients. The tape was painlessly removed per vaginam as an office procedure 6 to 8 weeks later by cutting one end level with the vaginal mucosa, and pulling on the other. In the last 10 patients, care was taken not to extend the incisions beyond the bladder neck. All failed procedures due to excessive looseness were in this group.

Subsequent vaginal adjustment procedures. Patients with recurrence of stress symptoms had a second minor procedure performed, either suburethral tightening ("tuck"), or I-plasty(5) p 63-67).

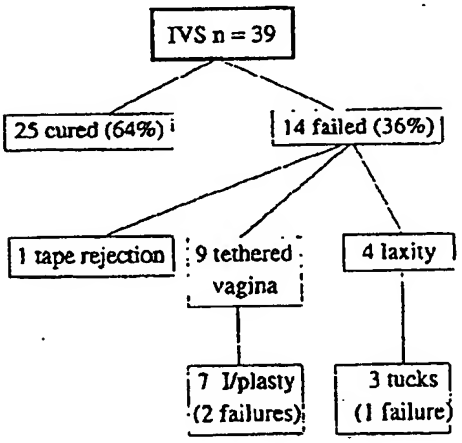
I-plasty procedure. This procedure was performed on 7 patients, and has been described elsewhere. Essentially, it consists of a 1-1.5 cm longitudinal incision in the vagina at the region of bladder neck, separation of vagina from the bladder serosa by wide lateral and posterior dissection, and resuturing of the incision horizontally. This manoeuvre effectively increases the amount of vaginal tissue in the bladder neck region. It was also performed under local anaesthesia/ midazolam, with 300 mls of normal saline in the bladder, so that the accuracy of the adjustment procedure could be checked by coughing during the operation.

"Tuck" procedure. This procedure was performed on 4 patients. Under local anaesthesia/midazolam, the bladder was filled with 300 mls of normal saline. In order to estimate how much tissue to excise for return to continence,the vagina was grasped paraurethrally with Littlewood's forceps ("Pinch Test") (8), and the patient asked to cough until continence was achieved. The "tuck procedure" was then repeated as above. Sufficient vaginal tissue was excised on both sides to ensure that continence was obtained.

RESULTS

Contact was maintained with all patients.

Table 1
Results - stress incontinence group



Flow chart indicating the reasons for failure and results of subsequent surgical corrections. Cure rate after adjustment = 90%.

Stress incontinence group. The results are summarized in Table 1. The minimal postoperative assessment period was 12 months, (mean 15 months). Total preoperative urine loss (57 patients), was 396.3 grams (mean 6.95 gm urine loss per patient). as compared to a total of 5.6 grams postoperatively in the 37 cured patients who were able to be tested (mean 0.15 gm urine loss per patient). Cough transmission ratio improved from a preoperative average of 70% to 87% postoperatively; preoperative maximal urethral pressure was 40.5 cm H2O. and this remained essentially unchanged postoperatively. Only one patient amongst those who failed was noted to have preoperative DI. There was no elevation of the bladder neck noted in any of the patients examined radiologically postoperatively.

A subsequent adjustment, Table 1, improved the total success rate to 90%, as determined by objective testing. Where both stress and urge symptoms were present, the operative cure of SI resulted in the simultaneous cure of both symptoms in the vast majority of patients. There was no new incidence of urgency in this study. Postoperative catheters were not used, and there was no postoperative urinary retention in this study.

Urge incontinence group.
All 18 urge incontinence patients were fully assessed postoperatively urodynamically, radiologically, and by pad testing. Sixteen patients were cured of their urge incontinence with the initial procedure. indicating a cure rate of almost 90% over a minimal period of 18 months. Only 4 of the 16 patients were noted to have preoperative "detrusor instability" (DI), as defined by a 15 cm H2O rise in bladder pressure on fast-fill supine cystometry; average maximal urethral pressure was 53 cm H2O; preoperative cough transmission ratio averaged 96%. All 16 cured patients were tested postoperatively. Four of these were found to have completely asymptomatic detrusor instability on urodynamic testing, and in only one patient was it present preoperatively.

Flow.
In both the urge and SI groups, the average preoperative urine flow was 28 mls/sec while postoperative flow was 26 mls/sec.

Complications.
Two patients developed suprapubic abscesses after tape removal. These were successfully treated with oral antibiotics. The bladder serosa was perforated anterolaterally by the tunneller on 2 occasions, and was recognized intraoperatively by the blood stained urine and by cystoscopic examination. The tape was withdrawn and reinserted without any complications. The catheter was left in overnight in these patients. Half of the patients reported a painless discharge which disappeared immediately the tape was removed. Some suprapubic discomfort was encountered by the 4th postoperative week in 25 % of patients, requiring early removal of the tape. in one instance. 31/2. weeks after insertion, without compromising the end result.

Operation characteristics.
(Slingplasty): operating time: 20-40 minutes: postoperative hospital stay: 6 to 24 hours; return to work: 2 to 10 days with no special precautions other than refraining from excess effort and intercourse; postoperative catheterization: nil.

DISCUSSION

Restoration of function by slingplasty: A lax vagina may not be able to achieve the "active closed position", so that the bladder neck remains "open" FIG 3, and the patient is susceptible to urine loss with stress.

Insertion of a tape (T), FIG 3 in the position of the pubourethral ligament (PUL) creates an artificial neoligament, against which PCM and LP can pull to close off the bladder neck.

Stress and urge symptoms may both derive from the same anatomical defect. Surgical cure of both stress and urge incontinence appears to confirm the main statement of the Integral Theory, (3), which states that the same anatomical defect, vaginal laxity at the bladder base, may cause both stress and urge incontinence. There was no new incidence of urge symptoms following this procedure, and no correlation was noted between preoperative detrusor instability

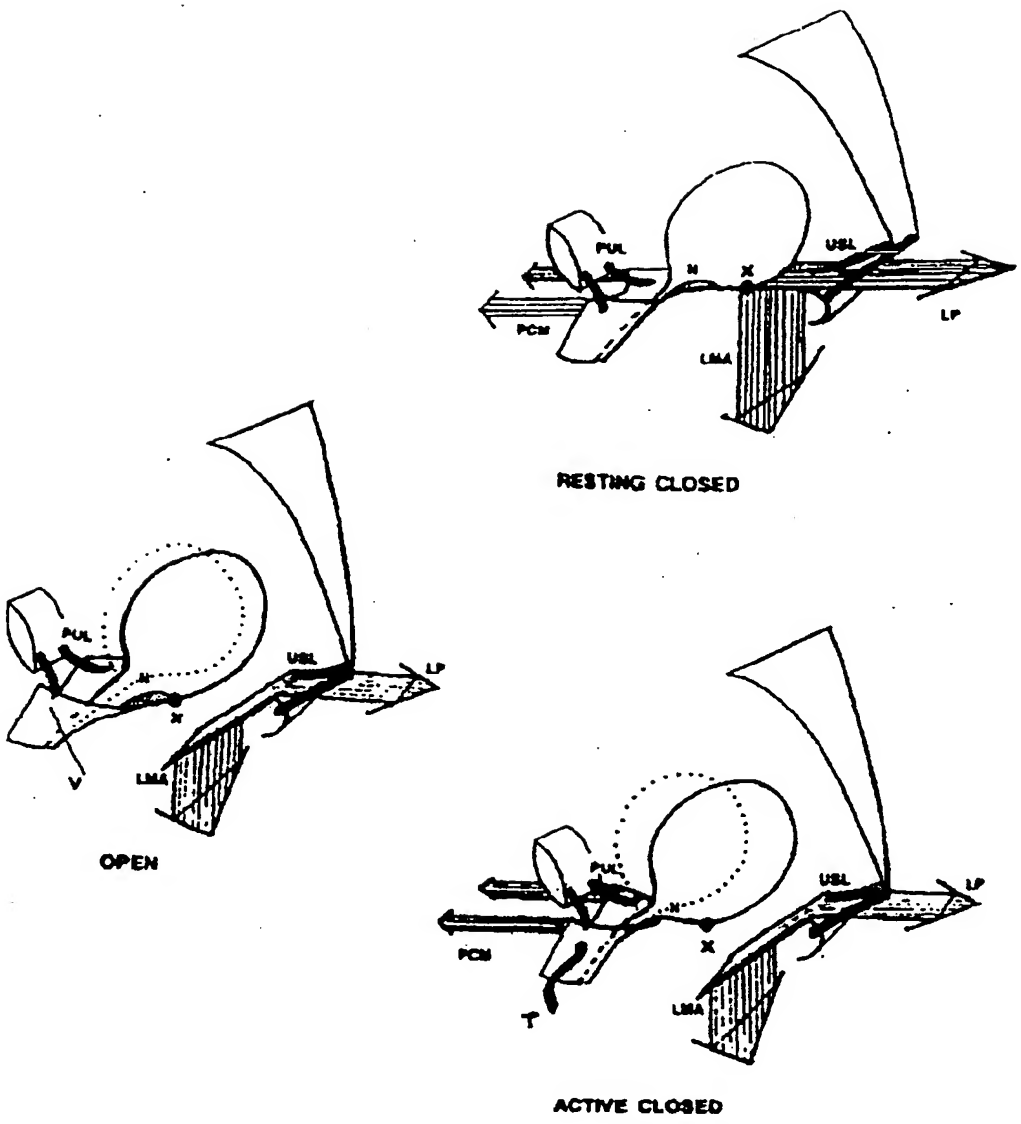


FIG 3

How the slingplasty restores normal function.

Reaction to "T" creates an artificial PUL fulcrum against which PCM and LP can stretch the vagina, to convert "OPEN" (incontinence) to "ACTIVE CLOSED" (continence).

Normal resting closed position: The anterior vagina is suspended superiorly by the arcus tendinous fasciae pelvis, anteriorly by the pubourethral ligament (PUL), and posteriorly by the uterosacral ligament (USL). The anterior vaginal wall (V) is attached to the bladder by the vesicovaginal ligament at (X). (N) = nerve endings at the bladder neck. (T) = Mersilene tape.

The arrow pointing to the left represents the forward contraction of the anterior portion of the pubococcygeus muscle (PCM). The arrow pointing to the right represents the backward contraction of the levator plate (LP) and the arrow pointing down represents the downward contraction of the longitudinal muscle of the anus (LMA), pulling down the levator plate. The position of the bladder in the "resting" position relative to that in the "open" or "active closed" position is indicated by broken lines.

and operative failure as suggested previously, (9). We attribute this to the bladder neck not being elevated. We attribute new incidence of bladder instability to irritation of "N" FIG 3 from below by the elevation process.

Aspects of tape implantation. The operation is converted to a minimal local anaesthetic procedure by means of the "tunneller". The design of the tunneller confers in-built safety to the procedure. The rigid tunneller ensures that there can be no wandering medially or posteriorly on insertion, towards the trigone or ureter. Perforation, on the rare occasions when it has occurred, has invariably been in the superolateral aspect of the bladder. In these instances, removal of the tape was much the same thing as removal of a suprapubic catheter. The presence of the tape facilitates drainage even when an infected haematoma forms. Our previous experimental animal studies (2), showed a far denser reaction at the vaginal end than the abdominal end with retropubic implantation of the tape. On this basis, it was considered that the potential problems of postoperative "weeping" suprapubically, and abscess formation could be solved by implanting the tape as two vertical pillars. This option is presently being pursued.

Relevance of dysfunctional anatomy to cough transmission ratio(CTR) and urge symptoms. We attribute the improved CTR in those patients with SI to tightening of the suburethral vagina (3). The low preoperative CTR in the SI patients is consistent with our concept (3), that SI is caused by a direct mechanical defect, a result of vaginal laxity. In the group with predominantly urge and few SI symptoms, the former are neurologically derived, being principally due to lack of inferior support for these nerve endings. Premature activation of these nerves may occur with a much more minor anatomical defect. This is reflected in a high pre-operative CTR. The aim of our surgical intervention was to restore the vaginal tension, restoring the mechanical closure mechanisms and, at the same time, supporting the nerve endings "N", preventing premature activation of the micturition reflex.

Effect of scarring/laxity at bladder neck. Adequate elasticity is required in the bladder neck region of the vagina for bladder neck closure to occur, (3). The high incidence of the "Tethered Vagina Syndrome" was probably due to scarring by the "tuck" incisions. This converts the vagina at bladder neck into a rigid connecting scar. On receiving the signal to close, LP, FIG 3, prevents PCM from closing the urethra. The bladder neck remains in the "open" position. This gives rise to the characteristic symptom of this condition, painless loss of urine prior to arrival at the toilet (5). This concept was proven by restoring elasticity in the bladder neck region of the vagina by a minor plastic operation, "I-plasty" (5). It was concluded from this, that in future, the vaginal incisions should not proceed beyond the bladder neck region in order to minimize scar formation.

Conclusions.

This study indicates how scarring in the bladder neck area of vagina may complicate female incontinence surgery. It also indicates that such scarring is potentially reversible, given that there is sufficient tissue to perform a z-plasty type of procedure (I-plasty) for restoration of tissue elasticity in this area, underlining the importance of conserving vaginal tissue when performing vaginal repairs.

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCES

(1) Petros P and Ulmsten U. The Combined Intravaginal Sling and Tuck Operation: an Ambulatory Procedure for the Cure of Stress and Urge Incontinence. Acta Obstet Gynecol Scandinavica (1990), Supplementum No 153, 69:51-57.

(2) Petros P, Ulmsten U and Papadimitriou J. The autogenic ligament procedure: a technique for planned formation of an artificial neo-ligament. Acta Obstet Gynecol Scandinavica (1990), Supplementum No 153, 69:41-49.

(3) Petros P and Ulmsten U. An Integral Theory of Female Urinary Incontinence. Acta Obstet Gynecol Scandinavica (1990), Supplementum No 153, 69:7-31.

(4) International Continence Society. Committee on Standardisation of Terminology of Lower Urinary Tract Function. Abrams P, Blaivas J, Stanton SI and Andersen JT (chairman) Scand J Urol Nephrol. (1988), Supplementum 114, pp 5-19.

(5) Petros P and Ulmsten U. The Tethered Vagina Syndrome; Post-Surgical Incontinence, and I-Plasty Operation for Cure. Acta Obstet Gynecol Scandinavica (1990), Supplementum No 153, 69:61-65.

(6) Petros P and Ulmsten U. Cure of urge incontinence by the combined intravginal sling and tuck procedure. Acta Obstet Gynecol Scandinavica (1990), Supplement No 153, 69:59-60.

(7) Petros P and Ulmsten U. The Tuck Procedure, A Simplified Vaginal Repair for Treatment of female Urinary Incontinence. Acta Obstet Gynecol Scandinavica (1990), Supplementum No 153, 69:39-40.

(8) Petros P and Ulmsten U. The Pinch Test for Diagnosis of Stress Urinary Incontinence. Acta Obstet Gynecol Scandinavica (1990), Supplementum No 153, 69:31-33.

(9) Stanton S L. Colposuspension. Surgery of Female Incontinence 2nd Ed., (1986), Eds. Stanton SI. and Tanagho EA. Springer-Verlag Berlin. 95-103.

(10) Nordin M and Frankel VH. Biomechanics of Collagenous Tissues, In Basic Biomechanics of the Skeletal System. Eds Frankel VH and Nordin M. Lea and Febiger Press, Phil. 1980 pp 87-110.

ORIGINAL ARTICLE

FURTHER DEVELOPMENT OF THE INTRAVAGINAL SLINGPLASTY PROCEDURE - IVS III - (with midline "tuck").

Authors:
PE PAPA PETROS*, Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden.
and
U Ulmsten, PD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT

The intravaginal slingplasty operation (IVS III), was performed under local anaesthesia on an unselected group of 39 patients, mainly with pure stress or mixed incontinence. The artificial pubourethral ligament was created by insertion of two parallel columns of tapes. The suburethral vagina was tightened by excision of a midline segment of vagina not extending beyond bladder neck. At 12 months, the primary operation cured 70% of the stress incontinence symptoms, and 85% of the urge incontinence symptoms. A minor surgical tightening of the vaginal wall at a later date improved the total cure rate to 81% for SI. Operative failure was principally attributed to "visco-elastic creep", a subsequent loosening of vaginal tension. Further development is required to improve the primary cure rate.

INTRODUCTION

The intravaginal slingplasty (IVS) procedure (1) with large bilateral "tucks" failed probably because scar tissue from the bilateral "tucks" extended over bladder neck, preventing bladder neck closure, and causing the"Tethered Vagina Syndrome", (2).

The main conclusions from the IVS study with large bilateral "tucks" was that the vaginal part of the procedure should not extend beyond bladder neck, and that the tapes would be inserted as 2 parallel columns so as to prevent abscess formation after removal of the tapes. So as to minimize the amount of scarring in the bladder neck part of vagina, it was decided to perform a single midline incision, similar to that made in a Kelly repair up to, but not extending beyond, bladder neck.

PATIENTS MATERIAL AND METHODS

Patients An unselected group of 39 patients with a history of urinary incontinence were treated. Pure stress incontinence was objectively the major incontinence problem in 12 patients, pure urge incontinence symptoms in 2 patients, and painful urge symptoms in one. The remainder had mixed symptoms. Age ranged from 30 to 87 years (mean 55), parity 0 to 14 (mean 3.5), and weight from 48 to 115 kg (mean 66 kg). In the first instance, all patients had an intravaginal slingplasty with a single midline 'tuck' procedure performed, FIG 1. Owing to inadequate continence control, 10 patients had a further vaginal tightening performed between 1 and 3 months after the primary operation.

Diagnostic procedures. The test schedule was that the patients emptied their bladder first thing in the morning, took a vitamin B tablet containing 50 mg of riboflavine so as to stain the urine dark orange, drank between 1 and 2 glasses of water prior to departure, and presented for testing with a tolerably full bladder. Where possible, a further 1 or 2 glasses of water were ingested on arrival. The patient was initially tested for stress incontinence by placing a perineal pad over her vulva, and asking her to cough 10 times. Then she was asked to perform, if possible, 10 star jumps, (scissor jumps). The pad was examined at the end of each test and weighed if there was any staining. Urethrocystometry was performed essentially according to the method of Asmussen and Ulmsten (3),and included provocation with a straining, "cutting-off" and hand-washing.

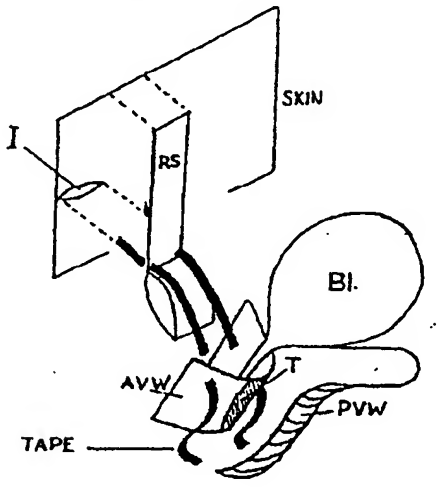


FIG 1
The intravaginal slingplasty procedure with midline "tuck".
T = "tuck"; I = incision in anterior abdominal wall; Bl. = bladder; RS = rectus sheath; AVW = anterior vaginal wall; PVW = posterior vaginal wall.

Surgical procedure. The insertion of the tunneller is as described previously (1). Preoperative single-dose intravenous flucloxacillin and 1 mg rectal metronidazole were used. The vaginal ends of the tapes were trimmed to a protruding length of 1.5 to 2 cm, and fastened to the vagina by a side-to-side suture which also transfixed the lower end of the tape.

Midline "tuck". The bladder was filled with 300 mls of normal saline. A midline incision was made, making sure that it did not extend beyond bladder neck. The flaps were dissected off the urethra. In order to estimate how much tissue to excise for return to continence, the two flaps of vagina were grasped paraurethrally with Littlewood's forceps, and the patient asked to cough until continence was achieved. Sufficient vaginal tissue was excised on both sides at the same time checking directly that continence was obtained. Postoperative catheterization was routinely omitted in these patients. The tape was painlessly removed per vaginam as an office procedure 6 to 8 weeks later simply by pulling on the protruding vaginal ends.

Criteria for cure. The patients were assessed using a structured semi-quantitative questionnaire by an independent external observer. They were also asked to assess what percentage cure had been achieved.

RESULTS

Contact was maintained with all but one patient. The mean postoperative observation time was 12 months, calculated after the last procedure if a postoperative adjustment was made.

At completion of the primary operation, almost all of the patients were completely cured of SI. As the operations were almost entirely performed under local anaesthesia, we were able to excise the precise amount of vaginal tissue necessary to achieve continence. However, at 12 months, only 26 of 37 patients with symptoms of SI (70%)and 23 of 27 of patients with symptoms of urge incontinence (85%) remained cured. Recurrence of SI, when it occurred, invariably did so within 2 months in this group of patients. One of 2 patients with pure urge incontinence, and 1 patient with painful urge symptoms were cured. A further suburethral vaginal tightening was made in 11 of the failed SI patients. This improved the cure rate for SI to 81%. A further 8% reported an improvement. Stress and urge symptoms, where present, were simultaneously cured in the vast majority of patients. There was no new incidence of urgency. Postoperative catheters were not used, and there was no postoperative urinary retention.

Complications. There were no postoperative infected retropubic haematomas. The bladder was perforated by the tunneller on one occasion. This was recognized intraoperatively by the blood stained urine and by cystoscopic examination. The tape was withdrawn and reinserted without any complications. The catheter was left in overnight in this patient. Half of the patients reported a painless vaginal discharge which disappeared immediately the tape was removed.

Operation characteristics (Slingplasty): operating time: 20-40 minutes; postoperative hospital stay: 6 to 24 hours; return to work: 2 to 10 days with no special precautions other than refraining from intercourse; postoperative catheterization: nil.

DISCUSSION

The simultaneous cure of stress and urge incontinence again confirmed the main statement of the Integral Theory (3), which states that the same anatomical defect, vaginal laxity is mainly responsible for both symptoms. There was no bladder neck elevation in this operation, indicating that the important cure factor was creation of an artificial pubourethral ligament, and adequate tensioning of the suburethral vagina. Implantation as 2 parallel columns appears to have improved the problem of postoperative suprapubic "weeping" and eliminated the small but bothersome postoperative infected haematomas caused by pulling on the inverted "U" configuration of the tape during removal.

Recurrence of symptoms. The exact amount of vagina was excised intraoperatively, restoring continence with a full bladder during coughing. We attribute the postoperative recurrence of suburethral laxity and stress incontinence to the process of "visco-elastic creep" (5), i.e. the force of muscle contraction re-arranges the ground substance of the vaginal connective tissue, in effect averaging out the force acting over the whole vagina, resulting in a relative loosening of the suburethral vagina, re-creating a mechanical closure defect.

Conclusions.

There were no cases of "tethered vagina syndrome", indicating the importance of leaving the bladder neck part of vagina free of scar tissue. However, we incurred the problem of postoperative "visco-elastic creep". Excision of additional vaginal tissue at the time of the initial operation is not an option for this procedure, as it carries a significant risk of causing the "tethered vagina syndrome. Therefore, in order to improve the primary cure rate, we need to be able to tighten the suburethral vagina in a way which prevents "visco-elastic creep", without compromising the elasticity in the bladder neck area.

Acknowledgement We would like to thank Dr Donald Clarke FRACOG for his assistance in the assessment process.

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCES

(1) Petros P and Ulmsten U. This issue.
(2) Petros P and Ulmsten U. The Tethered Vagina Syndrome; Post-Surgical Incontinence, and I-Plasty Operation for Cure. Acta Obstet Gynecol Scandinavica. Supplementum No 153, (1990), 69:61-65.
(3) Ulmsten U, Asmussen M, and Lindstrom K. A new technique for simultaneous uethrocystometry and measurements of the urethral pressure profile. Urol Int. (1977), 32:88-92.
(4) Petros P and Ulmsten U. An Integral Theory of Female Urinary Incontinence. Acta Obstet Gynecol Scandinavica. Supplementum No 153. (1990), 69:7-31.
(5) Nordin M and Frankel VH. Biomechanics of Collagenous Tissues, In Basic Biomechanics of the Skeletal System. Eds Frankel VH and Nordin M. Lea and Febiger Press. Phil. 1980 pp87-110.

THE FURTHER DEVELOPMENT OF THE INTRAVAGINAL SLINGPLASTY PROCEDURE: IVS IV - (with "double-breasted" unattached vaginal flap repair and "free" vaginal tapes).

Authors:
PE PAPA PETROS*, Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala. Sweden.
and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden.

ABSTRACT

The Intravaginal Slingplasty with "double-breasted" vaginal flap repair and free vaginal tapes as performed in 40 unselected patients with primarily mixed or pure stress incontinence solved the problems of "visco-elastic creep" and of the "tethered vagina syndrome", but had a primary cure rate of only 72%, due to the tearing out of either the internal or external flaps. Subsequent adjustment under local anaesthesia improved the cure rate to 92%. Further development of the vaginal part of this technique is required.

INTRODUCTION

The problem as identified in IVS 111 was how to prevent "visco-elastic creep", without creating a scar at the bladder neck, therefore risking occurrence of the " tethered vagina syndrome".

The anatomical basis for the "double-breasted" vaginal flap repair: the urethra is free of attachments in its upper 1/3. In the lower 2/3 of urethra, however, the vagina is densely adherent (1). It known that the vagina is elastic (2). We hypothesized that "visco-elastic creep" was essentially an equalization of tissue tension created by contraction of the pelvic floor, and that a "double-breasted" vaginal flap repair, FIG 1, sited at the lower 2/3 of urethra would ensure that there was no movement due to "visco-elastic creep" in the longitudinal axis because of the fibrous connection between the layers, as fibrous tissue is not elastic (3). Theoretically, stretching in the transverse axis should be unhindered. We considered that there would be no problems with inclusion cysts. The vagina has no glands, and there is no keratinization (1). During a 5 year personal experience in over 100 cases of the Raz "island patch" technique whereby a square patch of vaginal epithelium is buried below the vagina, no case of inclusion cyst formation (4) was found.

PATIENTS, MATERIAL AND METHODS

Patients. An unselected group of 40 patients with a history of urinary incontinence was treated. Pure stress incontinence was objectively the major incontinence problem in 13 patients, pure urge incontinence symptoms in 4 patients, and mixed symptoms in 23 patients. Age ranged from 17 to 79 years (mean 52), parity 0-8 (mean 2.4) and weight from 45-102 Kg (mean 62 kg). The patients were objectively assessed as previously described (IVS III).

Surgical procedure. A specially prepared 0.4 x 45 cm Teflon tape was used. The essential parts of the tape insertion were carried out as previously described (IVS III). The vaginal ends of the tape were sutured

to the vaginal mucosa, and trimmed, leaving 1-2 cm of tape protruding into the vaginal cavity. The inverted "U" was cut in its midpoint just above the level of the sheath, so that the tape now descended as two parallel lines behind the pubic symphysis.

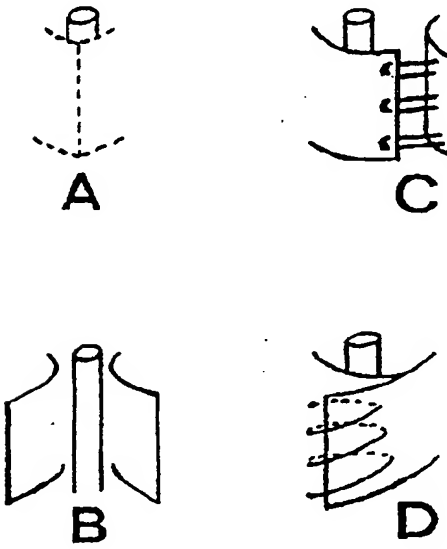


FIG 1
Double-breasted vaginal flap repair.
A = vertical incision in vagina; B = creation of flaps; C = fixation of inner flap ; D = fixation of outer flap.

The vaginal part of the procedure (FIG 1). The Foley catheter was re-inserted. Using a scalpel, flaps were created, FIG 1 A&B, stopping 0.5-1.5 cm short of bladder neck (avg. 1.0 cm), depending on whether the urethra is very long or very short. The superficial epithelial surface of the underlying inner flap was diathermied, and the flap secured to the inner aspect of the external flap using Sturmdorf-type sutures, FIG 1C. The external flap was then brought over and sutured to the outer surface of the inner flap using continuous 2-0 Vicryl sutures, FIG 1D. Postoperative catheterization was routinely omitted. The tape was removed per vaginam as an office procedure 6 to 8 weeks later by pulling on the vaginal ends.

RESULTS (Table 1)

Contact was maintained with all patients. Primary cure rate was 72%, (82% if part cure included). Assessment was by questionnaire and self-assessment of the patient, with overseeing of this by an external observer experienced in incontinence surgery.

TABLE 1

	pre-op	cured	cure after adjustment
UI only	4	3	3
SI only	13	6	12
Mixed SI / UI	23	19	22
TOTAL	40	28	37 %
CURE		(72%)	(92.5%)

The external flap tore out in 8 patients. Five of these were cured of their stress symptoms, but urge symptoms remained. A later re-attachment of the torn-out flap in 4 of these patients cured the urge symptoms. In 6 patients, the incontinence appeared to worsen, and the patients complained of "leaking all the time". The external flap appeared to be intact in these patients. Re-exploration by incision of the vagina in the midline, revealed that the urethra had become dilated and incompetent. Plication of the urethra, and re-tightening of the suburethral vagina restored continence dramatically in 4 of the 6 patients. The other two were cured of the symptom of "leaking all the time", but remained partly incontinent. There was no new incidence of urgency in this study. Postoperative catheters were not used, and there was no postoperative urinary retention. Almost all patients reported a non-bothersome postoperative thick yellow vaginal discharge, which cleared on removal of the tapes.

DISCUSSION

The results indicate that the double-breasting process appears to have achieved its primary objectives, to prevent postoperative "visco-elastic creep". We identify another problem, the potential tearing-out of the restraining sutures for the flaps.

Failure occurred primarily for mechanical reasons, tearing out either of the internal or external flaps. We hypothesized that a major reason for the external flap tearing out was that the unfixed edge of the external flap became devascularized, pre-disposing to the

sutures tearing through it. Also, the flaps were brought across under tension, predisposing to retraction. With regard to the inner flap, we consider that fixation by Sturmdorf sutures is a flawed technique, as it appears to predispose to retraction, fibrosis and urethral incompetence. Cure of urge symptoms after the loose flap was re-attached indicates the supportive function for the hypothesized bladder nerve endings at bladder base by vagina.

Conclusions.

The technique of fixation of both inner and outer flaps needed to be revised so that the fixation technique automatically predisposes to a) minimal tension on the flaps; b) adequate vascularization of the outer flap; c) the forces acting on the inner flap push it towards the urethra, not away from it.

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCES

(1) Krantz K. The anatomy and physiology of the vulva and vagina and the anatomy of the urethra and bladder. Scientific Foundation of Obstetrics & Gynaec. (1977), 2nd Ed, (Eds) Philipp EE, Barnes J, Newton M, William H Philadel. 65-78.

(2) Yamada H. Mechanical properties of urogenital organs and tissues in Strength of Biological Materials, (1970), Williams & Wilkins Co, Baltimore. Ed Evans FG. 205-218.

(3) Peacock EE. Structure, synthesis and interaction of fibrous protein and matrix. Wound Repair. (1984), 3rd Edition, Publishers WB Saunders Co, Philadelphia. 56-101

(4) McGregor B. Personal communication (1990)

ORIGINAL ARTICLE

FURTHER DEVELOPMENT OF THE INTRAVAGINAL SLINGPLASTY PROCEDURE: IVS V - (with "double-breasted" unattached vaginal flap repair and permanent sling).

Authors:
PE PAPA PETROS, Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden
and
U Ulmsten*, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT

Stress incontinence was cured under local anaesthesia in an unselected group of 47 patients with a history of either pure stress or mixed urinary incontinence by insertion of a permanent sling and by double-layer tightening of suburethral vagina. The primary cure rate was found to be 78% for stress incontinence. It was found that the external flap tore out in a large number of patients. When compared to the "free tapes" version (IVS IV), the primary cure rate with the permanent tape version was 10% superior. This indicates that the tape may provide an extra protective measure in cases where the vaginal part of the procedure fails, at least for stress incontinence. There were, however, some incidences of post-operative urinary retention.

INTRODUCTION

Even though the two elements necessary for successful surgery, re-creation of the posterior pubourethral ligaments, and adequate tightening of the suburethral vagina were ratified with each version of the IVS procedure to date, the proper restoration of function of the vaginal part of the procedure has remained a continuing problem. Another option considered was to create a more efficient bladder neck closure mechanism (1) by insertion of a permanent sling, a long Scandinavian tradition, but with several important differences: there was to be no elevation; the sling was not to be fixed superiorly; it was to be located at the mid-urethra; there was to be a concomitant "double- breasted" flap repair of vagina. It was felt important to continue with the tightening of vagina principally to provide support for the presumed nerve endings at bladder base, so as to prevent premature activation of the micturition reflex.

PATIENTS MATERIALS AND METHODS

Patients. An unselected group of 47 patients with a history of urinary incontinence were treated. Age ranged from 43 to 76 years (mean 52), parity 1-6 (mean 2.4), and weight from 47-96 Kg (mean 64 kg). Pure stress incontinence was objectively diagnosed in 35 patients, while 12 patients also had urge incontinence symptoms. All patients were fully tested urodynamically as described in IVS III. In 2 patients, Goretex was used, in 4 patients 4 mm Teflon was inserted. The remainder had 5 mm Mersilene inserted.

Surgical procedure This was performed entirely under local anaesthesia. Teflon, Mersilene or Goretex were used. Flaps were created and the operation performed as previously described (IVS IV), up to the point where the tunneller was inserted for the 2nd time on the contralateral side. Having checked cystoscopically that there was no tape in the bladder,

the outer sheath of the tunneller was removed, leaving the insert in situ. The free end of tape already in the vagina was then threaded into the eye of the needle, and the insert was pulled upwards. Care was taken to lie the tape flat across the mid-point of urethra, and to ensure that there was no tension at all suburethrally. The patient was asked to cough so as to test for continence, prior to proceeding to the vaginal part of the procedure. Finally the flaps were fixed with Sturmdorf sutures as in IVS IV. A No 8 hegar dilator was inserted into urethra, and pressed gently downwards so as to ensure that the sling was not interfering with the urethra. Postoperative catheterization was routinely omitted in these patients.

RESULTS

There were no intraoperative complications. Postoperative contact was maintained with all patients. Assessment was made by a third person skilled in incontinence surgery, using a standard questionnaire form, and by specific interrogation at a mean time of 12 months (range 6-18 months). Each patient was asked to assess her cure rate, whether she was completely cured or improved to >50% or >75%, or whether the operation had failed. All patients were tested with cough provocations with a comfortably filled bladder in supine and standing positions.

The primary operation completely cured 37 patients (78%) with symptoms of SI, while 6 patients (13%) reported more than 75% improvement, i.e. the patient leaked urine only occasionally at severe cold episodes etc. These latter 6 patients considered themselves as restored to a "complete normal life". Of the 12 patients with also symptoms of urge incontinence, 4 were entirely cured. The remaining 8 patients still reported urgency symptoms, but only two had incontinence. There was no new incidence of urgency in this study. In 2 patients, a sinus formed at 2 and 3 months postoperatively, requiring removal of the sling. Both patients had Goretex sling. Continence was maintained after sling removal. Postoperative catheters were not routinely used. There was postoperative urinary retention in 4 patients. Three were able to urinate within 24 hours. One patient required catheterization for a week. In four SI patients (9%) the operation failed. In two this was obviously due to failure of the vaginal plasty (flaps tearing out) as seen already after 4-6 weeks. In the remaining two failures no obvious reason for the failure could be shown. Thirty-five patients were urodynamically examined before and after the surgery. There were no significant changes in the urethral pressure profile. In patients cured the urethral closure pressure was positive in all but two. No de novo detrusor instability was recorded postoperatively.

DISCUSSION

Advantages of the permanent tape. When compared to the results of the "free tapes version" (IVS IV), the results indicate that the use of a permanent sling gives an extra dimension of strength to the procedure, at least as concerns the surgical cure of stress incontinence. Leaving the tape in creates a fairly strong inferior fulcrum for the bladder neck closure mechanism and providing a back-up mechanism for continence, if the internal layer of the "double-breasted" tuck loosens. Such a firm inferior fulcrum may not be possible in patients with "free tapes". They rely on the actual vaginal tissue to be sufficiently strong to provide this inferior fulcrum. The failure to cure urge symptoms comprehensively we attribute to the tearing out of the outer flap, preventing the vagina from being tensioned sufficiently to prevent the nerve endings at the bladder neck from firing off. In these situations, further postoperative tightening of the vagina is necessary to cure any residual urgency. Clearly, such tearing out indicates that the methodology for fixation of the flap was faulty. The edge of the outer part of the flap cannot undergo healing by primary intention. Instead, it relies on the process of healing by secondary intention, the inner surface of the outer flap to the outer burnt part of the inner flap. Whereas theoretically, the arrangement of sutures was to allow sliding of the outer flap if the apposition was too tight, this did not necessarily happen. The presumed devascularization of the edge of the outer flap probably allowed the sutures to tear through the now devitalized edge of the outer flap. On inspection this appeared to be the case.

Conclusion.

This technique seems to give overall acceptable cure

of >90% in patients with SI and combined SI and UI. Since the patients have been followed for only one year the definitive cure rate has still to be awaitied for another 2-3 years. It seems, however, justified to conclude that the described procedure should be considered a promising alternative for surgical cure of female urinary incontinence. The results also imply that then free tapes version could be improved by "crossing over" the tapes to create a firm fibrous suburethral band to facilitate the "kinking" of the bladder neck closure mechanism.

CORRESPONDENCE:
U. Ulmsten
Dept of Obstetrics and Gynaecology
Uppsala University
Akademiska sjukhuset
Uppsala, Sweden
Fax: 46 18 55 97 75

REFERENCE

(1) Petros PE & Ulmsten U. An Integral Theory of Female Urinary Incontinence. Acta Obstet. Gynecol. Scandinavica. (1990). Supplementum No 153, 69:7-31.

ORIGINAL ARTICLE

THE INTRAVAGINAL SLINGPLASTY PROCEDURE: IVS VI - further development of the "double-breasted" vaginal flap repair - attached flap.

Authors:
PE PAPA PETROS*, Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australi, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden
and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT

The principal aim of this study was to create a more efficient method of suturing the vaginal flaps using the "double-breasted" flap repair technique. in order to prevent tearing out, a principal reason for postoperative failure. The preliminary results in 21 patients using both "free tapes" and permanent sling methods indicate that the new technique appears give a markedly improved primary cure rate.

INTRODUCTION

The "double-breasted" flap repair technique as used in the Intravaginal Slingplasty IV and V appeared to have solved previous problems of "visco-elastic creep" and of the "tethered vagina syndrome" as causes of postoperative failure. However, the new method of creating the "double-breasted" flap repair was clearly faulty. Analysis of the previous methodology with regard to the biomechanical principles as described in Parts II & III, indicated that mechanical failure could be solved by ensuring that the flaps were not pulled across under tension, that devascularization of the external edge of the flap could theoretically be prevented by creating a cut edge in the internal flap, FIG 1, ensure primary re-vascularization, and tissue healing by primary intention. We regard urethral dilatation by fibrous retraction of the inner flap as a major potential problem. We proposed plication of the outer surface of urethra where it was lax, a more precise method of fixing the inner flap to the lateral side of urethra, and the insertion of tension sutures on the outer surface of the inner flap, so that they automatically compressed the inner flap towards the urethra on effort, FIGS 1-3. These tension sutures should also help protect the suture line of the external flap FIGS 1&2.

MATERIALS AND METHODS

Patients. An unselected group of 21 patients with a history of urinary incontinence was treated. The patients were pre-operatively assessed as previously described (IVS III). Teflon tapes were inserted as before and left free in the vagina in 12 patients, and as a permanent sling in 9 patients. Pure stress incontinence was objectively the major incontinence problem in 4 patients, and mixed symptoms in the remainder. Age ranged from 39 to 76 years (mean 51), parity 1-5 (mean 3), and weight from 48-82 Kg (mean 63 kg).

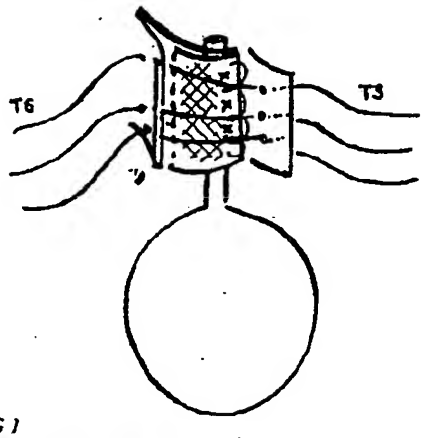
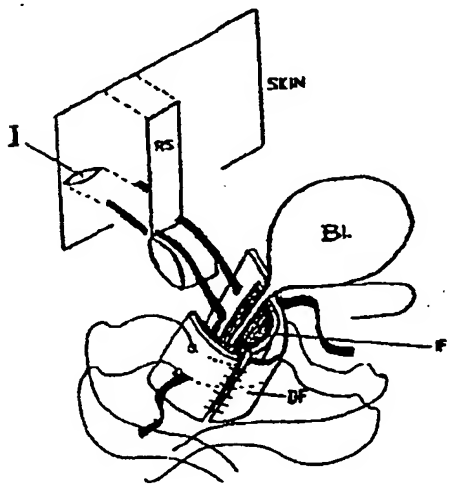


FIG 1
Fixation of inner flap
The inner flap has been sutured paraurethrally on the left side with interrupted and continuous sutures. The broken lines on the patient's right indicate the position of the vertical incision which has been made on the epithelial surface of the inner flap. TS = tension sutures.



IVS — removable tapes

FIG 2
Fixation of the outer flap - "free tapes".
This is a schematic representation of the completed operation. IF = inner flap; OF = outer flap; Bl = bladder; RS = rectus sheath; I = 1.5 cm skin incision.

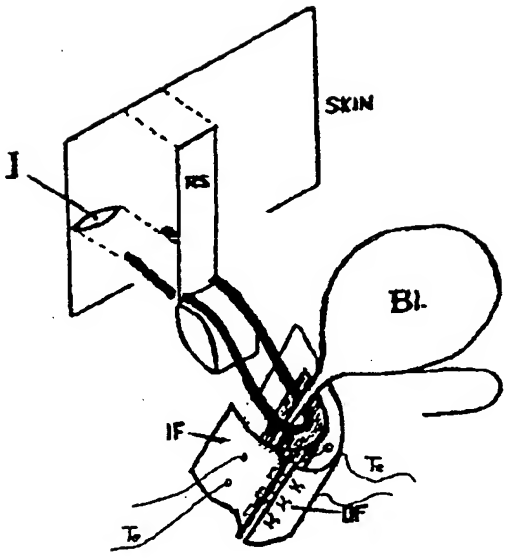


FIG 3
Fixation of the outer flap - permanent sling.
This is a schematic representation of the completed operation. IF = inner flap; OF = outer flap; Bl = bladder; RS = rectus sheath; Te = tension sutures; I = 1.5 cm skin incision.

Tape was inserted and flaps prepared as previously described (IVS IV). The 1st flap was gently pulled across the midline and sutured to the paraurethral tissue just lateral to the urethra using 2 to 3 interrupted 000 Vicryl sutures, and then with a second continuous suture. The superficial epithelial surface of that part of the inner flap to be buried was diathermied. A vertical incision was made on the epithelial surface of the inner flap down to the muscularis layer of the vagina, FIG 1, so that when the 2nd flap was gently brought across the midline, it could be sutured to the vertical cut surface of the inner flap, without any significant tension. Two or three 00 Vicryl "tension" sutures, FIG 1, were inserted, taking care that the suture passed outside the inner flap, FIG 1. The external flap was then sutured to the incised epithelium using 000 horizontal mattress sutures, FIGS 2&3, and the 'tension' sutures loosely tied over a pair of suture scissors, leaving a 1cc gap between sutures and vaginal epithelium.

Postoperative catheterization was routinely omitted in all patients. The tape was removed per vaginam as an office procedure 6 to 8 weeks later by pulling on the vaginal ends.

RESULTS (Table 1)

At 3 months

Contact was maintained with all patients. Assessment was by questionnaire and self-assessment of the patient, with overseeing of this by an external observer experienced in incontinence surgery. The external flap tore out in 3 patients postoperatively, a consequence, we believe, of postoperative coughing or vomiting attacks. Despite this, at 12 weeks, 19 patients reported more than 90% primary cure of their SI symptoms. Of the 3 who tore the external flap, one was cured of SI, but complained of urge symptoms. These disappeared immediately the flap was re-approximated 12 weeks later. The 2nd was more than 50% improved. The 3rd was a total failure. Four patients reported continuing urgency postoperatively, but these symptoms settled within 2 weeks. Three patients complained of increasing suprapubic pain postoperatively, usually beginning on the 3rd postoperative day. This continued until the lower tension sutures, FIGS 1&2 burst or were cut. One patient with a permanent sling could not urinate postoperatively, and required catheterization for 24 hours.

At 9 months

Of the 19 cured patients, 18 were assessed after a further 6 months. Only one reported partial recurrence of symptoms, and this appeared to be due to suburethral vaginal laxity.

DISCUSSION

The problem of the flaps tearing-out of sutures appears to have been mostly solved using this technique. The results, albeit preliminary, emphasize that attention must be paid to the biomechanical aspects of connective tissue, i.e. the structural strength of vagina, its elasticity, the muscular forces to which it is subjected, and, above all, how the surgical technique used may either protect or predisposes to rupture of the suture line. With regard to the latter, we stress that the flaps must not be pulled over too tightly. The improvement in postoperative urge symptoms we attribute to subsequent "visco-elastic creep" lessening the upward tension we presume caused these symptoms in the first place.

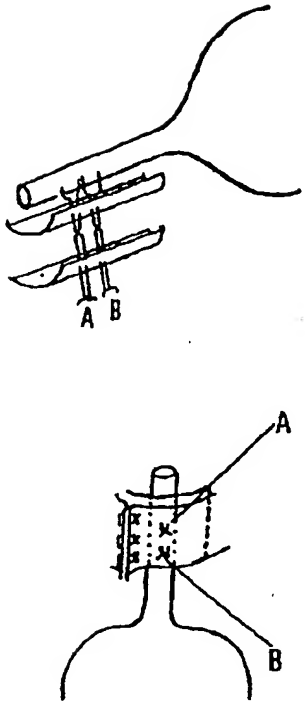


FIG4

Improved Periurethral anchoring of vaginal flaps

After the flaps have been opened out, 2 anchoring sutures, A & B are inserted deep into the paraurethral tissues, and brought out through both flaps as indicated, fixing each flap in turn with the same sutures. Care must be taken not to tie the sutures too tightly. If a urethral plication is made, then the same sutures can be brought through the flaps. This manoeuvre also assists fixing of the flaps, which still has to be performed as indicated in FIGS 1,2 &3.

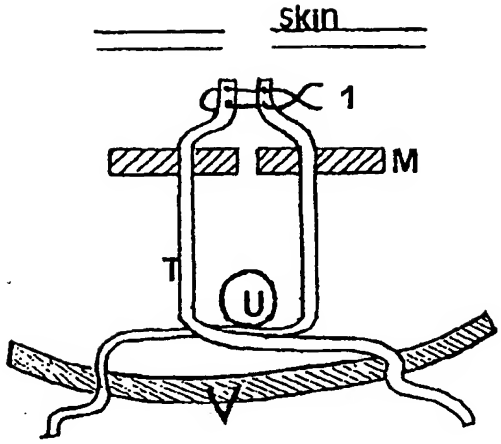


FIG5
"Cross-over free tapes"
The tapes are crossed directly below the urethra, taking care that they are situated well forward of the mid-urethra. They are tied superiorly ONLY with No1 Vicryl, and left entirely free at the vaginal level. This ensures that there can be no injury to the urethra. T = tape; U = urethra; V = vagina; M = rectus muscle.

Conclusion

Use of tension sutures may sometimes cause pain, especially if tied too tightly. *Analysis of this surgical variation with regard to the normal anatomy (1) indicates that attachment paraurethrally or to the urethra itself would better re-create the dense fibrous tissue attachment of urethra to vagina.* Attachment in the manner of FIG 4 is already being performed. Preliminary results (unpublished data) are most optimistic, indicating that the vagina is firmly attached, without post-operative pain. However, we have found that there is a much greater possibility of post-operative urinary retention, especially if the attaching sutures proceed beyond mid-urethra. Experience using the permanent sling suggest that a "cross-over" method of tape insertion in the "free tapes" version of this procedure, FIG5, would give most of the advantages of a permanent sling. Preliminary results are optimistic.

Postscript

As a general comment, many patients whom we had regarded as being total operative failures with the IVS IV, V and VI versions subsequently reported a significant improvement in their stress incontinence symptoms(unpublished data). We attribute this to the tightening which would result from scar tissue contraction around the double flap repair, a result of inter and intramolecular cross-bonding.

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

ACKONWLEDGEMENT:
To Dr Harald Bratt and Proffesseur Per Johnson for discussions leading to improved technique as demonstrated in Figures 4 and 5 respectively.

REFERENCE

Krantz KE. Anatomy of the urethra and anterior vaginal wall. American J. Obstet Gynecol. (1950), 62:374-386.

ORIGINAL ARTICLE

THE FREE GRAFT PROCEDURE FOR CURE OF THE TETHERED VAGINA SYNDROME

Authors:
PE PAPA PETROS* Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden
and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT
Symptoms of stress and urge incontinence in 12/16 patients with the "tethered vagina syndrome" were substantially cured by insertion of a free graft in the vagina in the area of bladder neck. The operation works by restoring elasticity in the vagina below bladder neck, thus allowing the bladder neck and urethral closure mechanisms to operate independently.

INTRODUCTION

Urinary incontinence due to decreased elasticity in the vagina below bladder neck, ("tethered vagina syndrome"), has been previously described as an important cause of postsurgical incontinence (1). Surgical cure of such patients has been previously reported using the "I-plasty" operation. *In biomechanical terms, however, this operation cannot permanently restore elasticity in the bladder neck area of the vagina if there is a net deficit of tissue, due to previous vaginal excision, or if the elasticity in this area has been compromised by excessive elevation.* Initially the graft operation was performed in those patients who had failed I-plasty procedure (1), a technique which imports healthy vaginal tissue to the bladder neck area. Later it was performed as a primary operation in patients diagnosed as having the "tethered vagina syndrome".

PATIENTS, MATERIAL AND METHODS

A total of 16 patients were diagnosed as having the tethered vagina syndrome. Age ranged from 35 to 91 years, mean age 68 years. Parity ranged from 1-6, mean 3.

Pre and post operative assesment.
All patients were fully assesed as previously described IVS II-VI This issue.

Operation. A full thickness 4 cms long horizontal incision was made exactly in the transverse crease of the bladder neck area of the vagina, FIG 1. This was opened longitudinally with a pair of long handled scissors. Scar tissue below the vagina was excised. Haemostasis was ensured by diathermy. A 4 x 3 cm full thickness vaginal graft was taken from the posterior vaginal wall in the analogous position to the transverse incision, or as skin from the anterior abdominal wall or buttock. The vagina from whence it was taken was sutured in the anteroposterior direction to ensure that there was no narrowing at the site. Where relevant, the graft was trimmed of all underlying fat and sutured into the bladder wall initially with four quilted sutures and peripheral sutures 3 mm apart interrupted (3/0 Vicryl) No vaginal packs were applied and a catheter was put into the patient overnight only. Generally the patient was allowed to go home on the next day and instructed to rest at least for a week to allow the graft to heal.

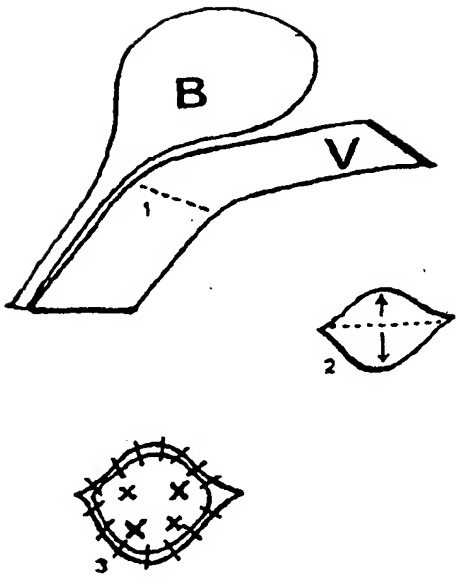


FIG 1
Free graft repair.
The numbers 1.2 & 3 denote the successive stages of the operative procedure. X = quilting sutures to the bladder tissue; B = bladder; V = vagina.

RESULTS

Twelve patients gave a history of having undergone a previous bladder neck elevation procedure, and 4 patients had undergone at least one previous vaginal repair. In all, more than half of the patients had undergone a previous failed I-plasty. Mean postoperative follow up was 9.2 months. Range 3-13 months.

Symptoms. All patients had symptoms of frequency, urgency and nocturia. Urge incontinence was present in 15 out of the 16 patients. All patients wet frequently prior to arrival at the toilet, and in 13/16 patients, this symptom was invariable. Stress incontinence with coughing was present in only 7 out of 16 patients. Another 7 out of the 16 patients complained of leakage either on bending over or during walking, but not on coughing. ie. paradoxical leakage (so named because of leakage at a lower pressure than on coughing). Maximal urethral pressure ranged from 8 to 52 cms mean 20 cms.

Radiological Diagnosis. In patients with a net deficit of elastic tissue in the interior vaginal wall, there may be very little movement of the bladder neck on straining (cf FIGs 11a, 11b Part I)

Surgical results. Eleven patients reported a cure rate of all symptoms in excess of 90%. One patient reported cure of her urge incontinence but continuation of her frequency. Four out of 16 patients reported a rejection of the graft. This generally occurred within the first week and in all cases a dark brown chocolate discharge was noted. There did not appear to be any greater rejection of skin as opposed to vaginal grafts. Where the operation was successful, symptoms took 2 to 4 weeks to improve. Thereupon, further improvement was noted over the next four months. One patient who was entirely cured reported return of incontinence symptoms 6 months postoperatively, though they were different to the original symptoms. Investigation demonstrated that the suburethral vagina had become very loose, we assume from too large a graft. A double flap repair performed under day surgery conditions with local anaesthesia completely cured this patient. All 4 patients who reported rejection of their flaps also reported worsening of their symptoms over the ensuing 6 months.

Skin Grafts: In 5 patients there was a net deficit of tissue in the posterior vaginal wall, so that there was insufficient tissue available to perform a graft. In these patients, skin was taken from the buttock or abdomen, trimmed and sutured accordingly.

Cough transmission ratio. This was more than 90% in 13 patients (in 9 patients it was more than 100%). In 2 patients however, the cough transmission ratio was in the range of 60-65%, and in one patient, 85%.

DISCUSSION

Modus operandi of the operation. The graft restored the elasticity at ZCE, (FIG 3 theory section), thereby permitting the urethral and bladder neck mechanisms to function separately. Over-correction was noted in one patient, i.e. the suburethral tissues were rendered excessively loose. This demonstrates that 1) Precision is required for restoration of vaginal tension. 2) Such precision may not be entirely achievable using our present techniques. 3) Therefore, as an alternative, in order to achieve this precision, we

advise, in all operations, that further adjustment of the vagina may be necessary in up to 20% of patients. *Disadvantage of this procedure.* Rejection may lead to scarring and worsening of symptoms.

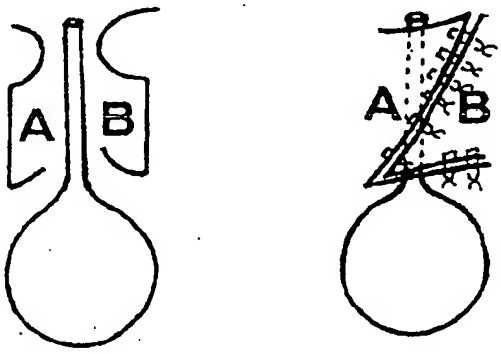


FIG2
Z-plasty for restoration of laxity to ZCE
The flaps A & B are mobilized. A is swung across the urethra, and B is swung down towards the bladder neck area of vagina.

Alternative procedure. If there is also an obvious suburethral laxity, then a simple z-plasty FIG2 may give good results (unpublished data), as it simultaneously tightens the suburethral vagina, and loosens the excessive tightness of vagina in the bladder neck area over the ensuing 6 weeks. This technique uses the process of "visco-elastic creep" to advantage. If there is also a net deficit of vaginal tissue in the anterior vaginal wall, combining the z-plasty FIG2 with say, a vulval flap to cover any bareness created in the suburethral vagina may create sufficient laxity in the "zone of critical elasticity" to restore the separate closure mechanisms.

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCE

Petros P & Ulmsten U. The tethered vagina syndrome, postsurgical incontinence and I-plasty operation for cure. Acta Obstet et Gynecol Scand. 1990; Suppl. No 153, 69:63-67.

ORIGINAL ARTICLE

THE POSTERIOR FORNIX SYNDROME: A MULTIPLE SYMPTOM COMPLEX OF PELVIC PAIN AND ABNORMAL URINARY SYMPTOMS DERIVING FROM LAXITY IN THE POSTERIOR FORNIX OF VAGINA.

Short title: Posterior fornix syndrome. Key words: Pelvic pain, dyspareunia, "obstructed" flow , urge incontinence, stress incontinence, residual urine, hysterectomy.

Authors:
PE PAPA PETROS* Dr Med Sc MRCOG FRACOG Dept of Gynaecology Royal Perth Hospital Perth, Western Australia, Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden
and
U Ulmsten, MD PHD Dept of Obstetrics and Gynaecology Uppsala University Akademiska sjukhuset Uppsala, Sweden

ABSTRACT

The "posterior fornix syndrome", as studied in 28 patients, is described. It consists of multiple symptoms of pelvic pain and abnormal urinary symptoms deriving from laxity in the posterior fornix of vagina. The symptoms encompassed include pelvic pain (32%), deep dyspareunia (39%), symptoms of stress (32%) and urge (39%) incontinence, those associated with defective bladder neck opening (35%), and high residual urine (52%). The percentage incidence of symptoms, as denoted by brackets was expressed as a percentage of 28. and were only attributed to this syndrome if they abated after surgical cure. A simple posterior fornix repair performed under local anaesthesia cured more than 50% of the symptoms in each category, indicating that laxity in the posterior vaginal fornix was most likely the prime cause of these symptoms.

INTRODUCTION

The role of the uterosacral ligaments and posterior wall of vagina has received scant attention as concerns their pathogenesis in pelvic pain and female incontinence. Cure of symptoms including collision dyspareunia, low abdominal pain, low sacral backache, and urge symptoms by laparoscopic ventrosuspension and hysterectomy has been reported previously (1).

In a preliminary report, we confirmed (2) that not only urge, but also stress symptoms could be caused by laxity in the uterosacral ligaments, and that both were frequently curable by a simple posterior fornix repair. The theory predicted that such vaginal laxity may also be a cause of high residual urine, and symptoms of defective bladder neck opening (3). (Relevant symptoms are detailed in Appendix A). The aim of this study was to test previous findings (1)(2), and to further investigate clinical and urodynamic manifestations of laxity in the posterior vaginal fornix.

PATIENTS, MATERIALS AND METHODS

Twenty-eight patients were studied. Mean age was 45 years (renge 32-71) parity 2.7 (range 0-6). Inclusion criteria were based on having either low pelvic pain or collision dyspareunia not of inflammatory origin, Appendix A, a residual urine of more than 50 mls in patients without previous incontinence surgery. or more than one symptom of defective bladder neck opening as detailed in Appendix A.

The patients arrived for testing with a comfortably full bladder. Objective testing included special exercise pad tests, Urine loss, if any, was measured during provocation with 10 coughs and 10 star jumps. Urethrocystometric testing was performed according to (4) and included pressure transmission ratios (PTR) during coughing, straining, and "cutting-off" in the supine position, and a hand-washing test for urge incontinence and bladder instability performed in the standing position. Urinary flow studies, bladder volume, and residual urine estimations were also performed. A pessary was inserted as described (1) in 50% of the patients.

Operation. The posterior fornix repair was performed entirely under local anaesthesia, often as an office procedure. The patient was placed in the lithotomy position. The corners of the posterior fornix were gently grasped by Littlewood's forceps without applying pressure. Using long needle, preferably with a shield over the point (e.g Cobak), the vaginal mucosa was infiltrated with 5-10 mls of 0.5-1% xylocaine with 1/200,000 adrenalin on each side extending to the midline, grasped firmly with Littlewood's forceps, and pulled laterally and forwards. Under tension, a full thickness horizontal incision was made with a scalpel between the forceps. The points of long-handled scissors were inserted antero-posteriorly in the incision, and the handles opened out, i.e. the scissor points stretched open the incision in an antero-posterior plane. If possible, the uterosacral ligaments were identified, approximated in the midline, followed down posteriorly and further approximated. No1 Vicryl was used, and the needle point frequently used to locate the often deeply set ligaments. The vaginal mucosa was then approximated from side to side. Care was taken to approximate the tissues without excessive tension. If an enterocoele or high rectocele were present, they were appropriately repaired at the same time in the surgical theatre.

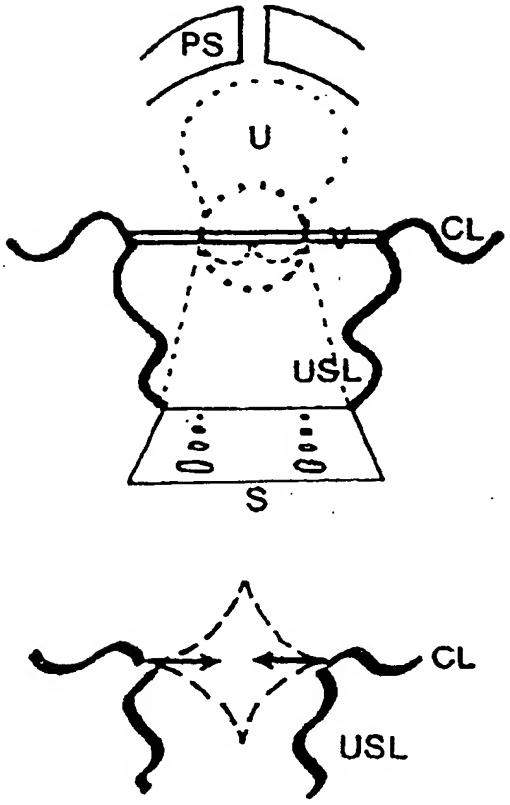


FIG 1
How hysterectomy may create a posterior fornix defect.
This is a schematic view of the pelvis as seen from above. PS = pubic symphysis; USL = uterosacral ligament; CL = cardinal ligament; V = vagina; S =, sacrum; U = uterus; in the upper diagram, the broken lines indicate the pre-operative state the solid lines indicate how suturing the vault horizontally loosens it's ligamentous support from CL and USL; in the lower diagram, the arrows indicate how CL and USL may be tightened by suturing a horizontal posterior fornix incision from side to side.

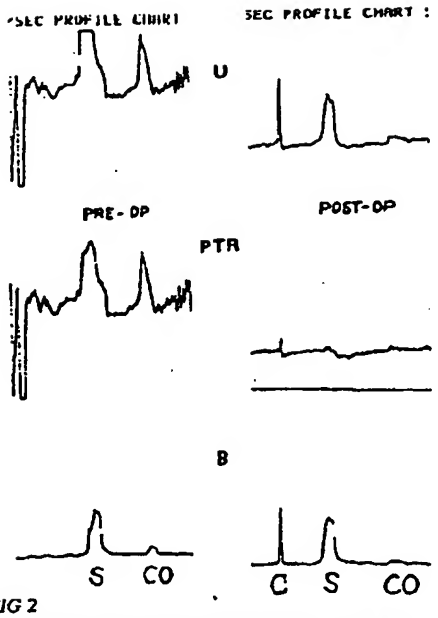


FIG 2
Conversion of pressure transmission ratio after posterior fornix repair.
This is a pressure transmission graph of the same patient with readings taken immediately before and after a posterior fornix repair. U = urethral channel; PTR = subtractor channel; B = bladder channel; S = strain; C = cough; CO = cut-off.

Postoperative assessment. The postoperative assessment was performed by a third person, trained in female incontinence, and using the questionnaire, Appendix A, personal interview, and objective testing as above. The results were entered onto a data base, and subsequently analysed. No patients were lost from the study. The symptoms were only attributed to this syndrome if they abated after surgical cure, Tables I & III.

RESULTS

The postoperative assessment was performed between 4 and 30 months postoperatively (mean 12 months). The results are summarized in tables I, II & III. In 19 patients, mean residual urine was reduced from 123 mls preoperatively (range 500 mls to 2 mls) to 31 mls postoperatively (range 150 mls to 0 mls). The peak flow was virtually unaltered, 30 mls/sec. postoperatively, as against 28 mls/sec preoperatively.

In 7 patients with a positive Valsalva pressure transmission ratio (PTR) and symptoms of urinary incontinence, the Valsalva PTR was repeated immediately after the procedure had been performed under local anaesthesia. All 7 readings converted from positive to neutral or slightly negative, FIG 2. We confirmed that symptoms, including high residual urine, may be greatly improved after pessary insertion.

TABLE I (28 Patients)

symptom	cured	improved	true frequency of symptoms*
stress incontinence n = 19	9	4	32%
urge incontinence n = 21	11	3	39%
defective opening n = 16	10	-	35%
low pelvic pain n = 12	9	-	32%
deep dyspareunia n = 16	11	-	39%
residual urine n=19	10	-	53%

* Symptoms were expressed as a percentage of 28 and only attributed as part of the posterior fornix syndrome if cured.

TABLE II - VALSALVA PTR

	Positive	Negative
stress incontinence n = 19	12	7
urge incontinence n = 21	13	8

TABLE III
(14 HYSTERECTOMY PATIENTS)

symptom	cured	improved	failed
stress incontinence n = 9	6	3	0
urge incontinence n = 13	8	2	3
defective opening n = 8	6	-	2
low pelvic pain n = 7	5	-	2
deep dyspareunia n = 7	4	-	3

DISCUSSION

Clinical diagnosis. The patient may have pelvic pain (cf "pelvic pain syndrome" (1), Appendix A), urgency (1), and varices noted laparoscopically at the site of the uterosacral ligaments (1). *We found that symptoms of stress incontinence, defective opening and findings of high residual urine, are also an important part of the syndrome.* As these symptoms may occur after (indeed be caused by) hysterectomy, we consider that the "posterior fornix syndrome" may be an appropriate term. The high correlation between symptoms of incontinence and a positive Valsalva pressure transmission test is a promising objective test. On examination there may be a bulge between the uterosacral ligaments, or presence of an early enterocoele. Insertion of a ring pessary may tighten the posterior fornix by stretching the supralevator vagina (we have demonstrated this radiologically) and bring a dramatic improvement in symptoms*. As such the pessary is a useful, but not infallible, predictive diagnostic test.

* If the pessary used is too large, pelvic pain and worsening of symptoms may result. If it is too small there may be little or no improvement in symptoms. (Unpublished to date)

Relationship of symptoms to hysterectomy and lax uterosacral ligaments. In a prospective study involving 36 patients, some with urinary symptoms, Parys et al (5) reported an almost 100% increase in symptoms of defective emptying, (Appendix A), almost a 50% increase in symptoms of frequency, urgency and nocturia as well as a 20% increase in symptoms of incontinence following hysterectomy. Langer et al (6) investigating a group of 16 women without urinary symptoms undergoing hysterectomy, found that hysterectomy did not cause symptoms of incontinence. We were able to substantially reverse a high proportion of symptoms, Table III with a posterior fornix repair, indicating that laxity in the posterior fornix may have been the ultimate cause of these symptoms. Such a reversal of symptoms would not be possible if partial denervation (7) of the pelvic floor was the principal causative factor for urinary incontinence

Pelvic pain. Traction of a retroverted uterus on the sensory nerve endings of the posterior pelvic wall has been cited as an etiological factor for pelvic pain (8). We confirmed previous observations (1), (2) that laxity in the uterosacral ligaments may cause pelvic pain and dyspareunia. Though a large proportion of the patients' symptoms were previously cured with hysterectomy (1), we found persistence of pelvic pain and dyspareunia in many patients who had undergone hysterectomy. Many reported improvement after posterior fornix repair, Table III. *We conclude from the above that if pelvic pain can be caused by hysterectomy, it cannot be the hysterectomy per se which cures the pelvic pain, but the concomitant surgical repair of the ligamentous supports of the posterior vaginal fornix performed at the time of the hysterectomy.*

Pathogenesis. Anatomically, any looseness in the vagina between the pubourethral ligament, and the uterosacral ligament may cause symptoms (3). Overdistension of the posterior fornix during labour, or transverse suturing of the vault during hysterectomy are hypothesized as being principal etiological factors (2), though we have seen it in a nulliparous patient, becoming symptomatic after menarche. Laxity of the supralevator vagina may not allow adequate tensioning of the vagina below the bladder neck nerve endings. This lack of underlying support may cause the nerve endings to fire off, prematurely activating the micturition reflex, resulting in symptoms of frequency, urgency nocturia.

Some surgical considerations. Though effective (1), we do not agree, on anatomical grounds, that laparoscopic ventrosuspension (1) is the appropriate treatment. This operation works by elevating the uterus via the round ligaments, which are not structural entities. Also, elevation may create a potential enterocoele space. Elevation of the uterus may cause frequency and urgency on its own account (9). The process of bladder neck opening requires that there be no laxity between anterior wall of rectum and posterior wall of vagina, i.e. a high rectocele, if present, also needs to be corrected, along with any enterocoele, or laxity in the uterosacral ligaments.

CORRESPONDENCE:
P.E.PAPA PETROS
14A/38 Ranelagh Crescent
South Perth WA 6151
Australia
Fax: 61-9-474 3766

REFERENCES

(1) Hastwell GB. Psychogenic pelvic pain or the Occult Prolapse Syndrome. Medical Journal of Australia. (1986),144:405-407.

(2) Petros P and Ulmsten U. The role of a lax posterior vaginal fornix in the causation of stress and urgency symptoms: a preliminary report. Acta Obstetricia et Gynaecologica Scandinavica 69, Suppl. 153, 71-73, 1990.

(3) Petros P and Ulmsten U. An integral theory of female urinary incontinence. Acta Obstetricia et Gynaecologica Scandinavica 69, Suppl. 153, 1-79, 1990.

(4) Ulmsten U, Asmussen M and Lindstrom K. A new technique for simultaneous uethrocystometry and measurements of the urethral pressure profile. Urol Int. (1977), 32:88-92.

(5) Parys BT, Haylen BT and Parsons KF. Urodynamic evaluation of lower urinary tract function in relation to total hysterectomy. Aust. NZ J. Obstet. Gynaecol. 30, 161-165, 1990.

(6) Langer R, Neuman M, Ron-El R, Golan A, Bukovsky I and Caspi E. The effect of total abdominal hysterectomy on bladder function in asymptomatic women. Obstet. Gynecol. 74, 2, 205-207. 1989.

(7) Smith A, Hosker G and Warrell D. Role of pudendal nerve damage in the aetiology of genuine stress incontinence in women. Brit. J. Obstet. and Gynaecol. 96, 29-32, 1989.

(8) Martius H, as quoted by Nijs P. Psychological aspects of pelvic pain experience. P 24-37 in Chronic Pelvic Pain in Women Springer - Verlag Berlin ED Renaer M, 1981.

(9) Hodgkinson CP and Kelly WT. Urinary stress incontinence in the female III. Round-ligament technic for retropubic suspension of the urethra. Obstet. Gynecol. 10:5, 493-499, 1957.

CB

JOURNAL OF ENDOUROLOGY
Volume 10, Number 3, June 1996
Mary Ann Liebert, Inc.

Use of Synthetic Material in Sling Surgery: A Minimally Invasive Approach

JEFFREY P. NORRIS, M.D., DAVID S. BRESLIN, M.D., and DAVID R. STASKIN, M.D.

ABSTRACT

Traditionally, autologous material has been favored over synthetic material in the construction of pubovaginal slings for the treatment of female stress urinary incontinence (SUI). This preference arose largely because of concern about an increased incidence of infection or sling erosion when synthetic materials are used. However, when care is taken to minimize the amount of synthetic material, reduce total operative time, and limit exposure of the material to the operative field, female SUI can be treated effectively with synthetic material with an acceptably low complication rate. Furthermore, utilization of slings constructed with artificial graft material can be minimally invasive, cost effective, and well tolerated.

INTRODUCTION

PUBOVAGINAL SLINGS have long been recognized as an effective treatment for intrinsic sphincter deficiency (ISD). In addition, sling procedures have been effective for anatomic genuine stress urinary incontinence (SUI), originally for patients with increased risk factors for failure (i.e., obesity, failed prior surgery, chronic obstructive pulmonary disease) and more recently as a primary intervention. A variety of synthetic materials have been used for sling procedures (Marlex, Silastic, Mersilene, Teflon, and Gortex).[1–6] Infection and erosion of these materials into the bladder, urethra, and vagina have been the principal risk factors associated with their use.

The majority of experience with artificial graft materials used for slings is via an abdominal or combined abdominal and vaginal approach. We have attempted to decrease the invasiveness and morbidity previously encountered with the use of synthetic sling procedures by incorporating the minimally invasive technique of endoscopic needle suspension surgery in the placement of an expanded polytetrafluoroethylene (Gortex; W.L. Gore & Associates, Inc., Flagstaff, AZ) suburethral sling. Our 6-year experience with this material has led us to believe that it can be used as part of a simple technique that is highly effective in correcting both genuine SUI and ISD. By avoiding an extensive abdominal incision and eliminating the need to harvest autologous material, the invasiveness of sling surgery is significantly reduced.

TECHNIQUE

For more than 6 years, we have been using Gortex patch slings for the management of SUI and ISD. In the evolution of the technique that we currently use, we have employed several measures specifically designed to keep the infection/erosion rate negligible. When utilizing artificial graft material, sterile technique is of utmost importance. The patient receives a full 10-minute vaginal preparation with povidone–iodine. Broad-spectrum antibiotics are given preoperatively and postoperatively for 5 days. Most importantly, we have significantly reduced the size of the patch. The average patch used in our patients is 3.5 × 1.5 cm (surface area 10.5 cm^2). We believe that the reduced surface area of synthetic material is integral to keeping the rate of patch infection down.

The width of the patch is determined by placing the tips of forceps in the lateral vaginal fornices at the level of the bladder neck (Fig. 1). The standard height of the patch is 1.5 cm. The rectangular patch is prepared on a separate table by running a 2-0 Gortex suture along both 1.5-cm edges. The patch is then soaked in antibiotic solution until it is ready to be incorporated.

Technically, the procedure is similar to the modified Pereyra procedure described by Raz.[7] We prefer a single midline anterior vaginal-wall incision to an inverted-U incision, as it allows the patch to be exposed to the incision line in one place as opposed to two. Reduced exposure of the synthetic material to the incision line should decrease the chances of contamination of the underlying patch. After sharp entry into the retropubic space

Urodynamics and Continence Center, Beth Israel Hospital, and Department of Urology, Harvard Medical School, Boston, MA

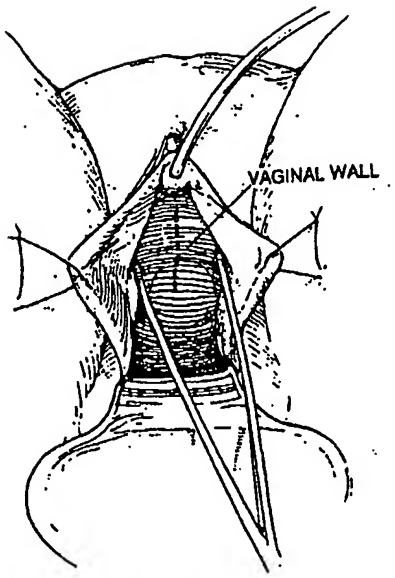


FIG. 1. Tips of forceps are placed in lateral vaginal fornices at level of bladder neck to determine appropriate width for patch.

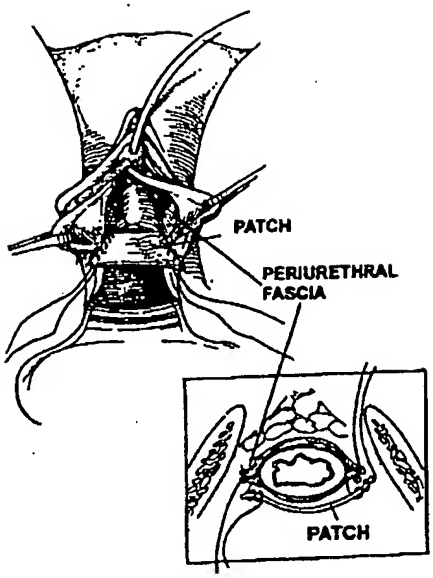


FIG. 2. Sutures of 2-0 Gortex are used to fix patch to periurethral fascia and pubourethral ligament.

through the vaginal incision, the patch is brought onto the surgical field, and the 2-0 Gortex sutures are secured to the mobilized edge of the periurethral fascia and the pubourethral ligament with a running stitch (Fig. 2). This fixes the patch and allows suspension of the bladder neck by the sutures alone without obstruction of the urethra.

The remaining steps of the procedure are similar to those of the standard needle suspension procedures. A suspension needle is used to bring all four suture ends through the retropubic space and out the lower abdominal wall (Fig. 3). In order to decrease patch exposure time, the vaginal incision is irrigated with antibiotic solution, the patch is centered over the bladder neck, and the vaginal incision is closed with absorbable suture prior to cystoscopy. Cystoscopy is used to confirm the absence of suture in the bladder and urethra and also facilitates placement of a percutaneous suprapubic tube. The sutures are tied without tension so the knot rests loosely on the rectus fascia. Care must be taken to avoid tension while tying these sutures in order to reduce the risk of postoperative urinary retention. The skin incisions are closed with subcuticular absorbable stitches.

RESULTS

We recently reviewed our experience with 122 patients who had undergone the procedure (mean follow-up 24.4 months). Many of these patients had failed prior surgery for SUI, and 57% had detrusor instability in addition to SUI. The average operating time was 80 ± 12 minutes. Complete resolution of SUI occurred in 88% of the patients. In the 15 patients with persistent incontinence, the average daily pad use decreased from 4.3 to 1.7, and six of these patients no longer needed to

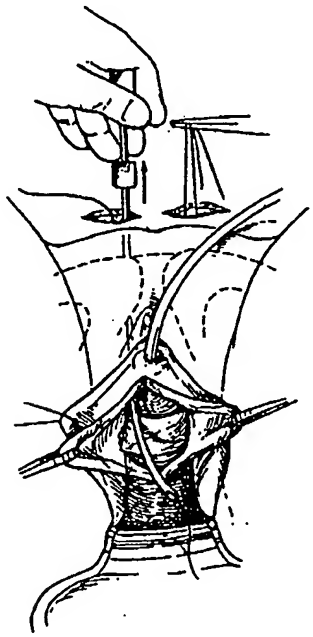


FIG. 3. Suture carriers are used to pull suture ends into retropubic space and out through abdominal wall incisions. Patch is centered beneath bladder neck, and vaginal incision is closed before sutures are tied.

wear any protective device. Fifty-one per cent (35/69) of the patients with preoperative detrusor instability and SUI had resolution of symptomatic detrusor instability following the procedure, while *de novo* symptomatic detrusor instability developed in 32% (17/53).

The average hospital stay was 24 hours, and 38% of the patients were able to have the suprapubic tube removed prior to discharge. Eighty-two per cent (100/122) of the patients had the suprapubic tube removed within 1 week. If urinary retention or severe obstructive voiding symptoms persisted beyond 12 weeks, the vaginal incision was reopened, and the sling was simply incised beneath the bladder neck. This maneuver was required in six patients, and SUI has not recurred in any of them.

Separation of the vaginal incision edges with exposure of the sling was observed in five patients and necessitated excision of the patch. These patients presented with watery vaginal discharge, and none experienced pain, fever, or an elevated white blood cell count. No patient has had erosion of the patch into the urethra or bladder. Only two of the five patients who have had their slings excised have experienced recurrent SUI.

The time to resumption of normal daily activities ranged from 2 to 12 weeks (mean 3.1 weeks). Seventy-eight per cent of the patients were happy with their decision to undergo surgery, 19% would not undergo the procedure again, and 7% were unsure.

DISCUSSION

The chief reservation about using synthetic materials in the construction of slings has been the risk of erosion and infection. In Bryans' experience[2] with polypropylene mesh hammock (Marlex), 5 of 69 patients (7%) had nonhealing of the vaginal wall. Morgan and associates[1] reported no vaginal erosions in 290 Marlex sling procedures; however, 2 patients experienced delayed erosion of the sling into the urethra at 1 and 3 years postoperatively. Chin and Stanton[3] reported erosion of Silastic slings in 10 of 88 patients (11%) (five vaginal, four bladder, and one urethral erosion). Bent and coworkers[6] reported a 20% removal rate of Gortex slings because of reaction/exposure of the sling at the abdominal or vaginal site. All excised slings were found to be colonized with gram-positive cocci. In their study, a 20 × 1.5-cm (surface area 60-cm^2) piece of Gortex was used as the sling. The surface area of the patch used in the construction of our slings (10.5 cm^2) is approximately one-sixth that of the Bent sling, and our erosion rate of 4% (5/122) is less by a similar factor.

Our experience with the Gortex patch suburethral sling has been positive in regard to overall success rate and patient satisfaction. Our follow-up to date has shown that this technique is as effective as the Burch procedure in the treatment of anatomic SUI; and as effective as the fascial sling procedure in the management of ISD. In addition, the patient is spared the morbidity of an abdominal incision and the harvest of autologous graft material.

It has been suggested that endoscopic needle suspension procedures fail because: 1) sutures tear from the vaginal wall, 2) sutures are placed laterally to avoid urethral obstruction, which may predispose to persistent urethral motion if the pubocervical fascia is deficient, and 3) ISD may coexist with genuine SUI and may be undiagnosed preoperatively. The use of a Gortex patch sling should reduce the failure rate, as the repair does not rely on the strength of the vaginal or pubocervical tissue, and it effectively treats both types of stress incontinence. The advantage over the fascial pubovaginal sling procedure is that our technique is performed with the facility of an endoscopic needle suspension procedure (familiar to most urologists) and there is no need for an abdominal incision. This makes for a shorter hospital stay and a quicker recovery time. Furthermore, we believe that synthetic material such as Gortex has the added benefit of being a permanent material that will not deteriorate with time. Longer follow-up is needed to determine if the use of synthetic materials in the construction of suburethral slings provides greater long-term success rates than those procedures that rely on the patient's own tissues for elevation of the bladder neck and compression of the proximal urethra.

Other procedures such as the laparoscopic Burch operation strive for the effectiveness of the retropubic bladder neck suspension with decreased morbidity. However, this procedure requires expensive equipment and prolonged operative time and has a steep learning curve and exposes the patient to serious risks such as vascular injury or perforation of a viscus. Radomski and Herschorn[5] recently reported an 85% success rate (mean follow-up 17.3 months) with the laparoscopic Burch procedure. The average operative time was 196 minutes with a mean postoperative hospital stay of 3.2 days. The Gortex sling procedure has a comparable success rate and decreased recovery time and can be performed with spinal instead of general anethesia. Also, it avoids the steep learning curve and the expense of extended operating room time. In addition, if ISD is present along with hypermobility, the laparoscopic Burch operation will be likely to fail.

CONCLUSION

The introduction of new surgical techniques and modification of existing ones is done with the intent of either decreasing the invasiveness of the procedure, simplifying the procedure, or improving its effectiveness. The use of synthetic materials in the construction of pubovaginal slings spares the morbidity of harvesting autologous tissue such as rectus fascia or fascia lata. In addition, the synthetic graft is inherently more durable than the patients own tissue, and this may explain why we have seen no recurrence of SUI in patients who have reported initial success. The Gortex patch sling technique we have described is technically simple and is effective in the management of Type II SUI and ISD. The procedure is performed with the facility of a needle suspension procedure but adds the benefit of a stable urethral backboard that is provided by all sling procedures. Overall cost and morbidity are decreased by reduced operating room expenses and hospital stay and by the rapid recovery. When care is taken to reduce the chances of patch infection, the advantages offered by the use of synthetic materials in the construction of slings should not be overlooked.

REFERENCES

1. Morgan J, Farrow G, Stewart P: The Marlex sling operation for the treatment of recurrent stress urinary incontinence: a 16-year review. Am J Obstet Gynecol 1985;151:224–226

2. Bryans F: Marlex gauze hammock sling operation with Cooper's ligament attachment in the management of recurrent urinary stress incontinence. Am J Obstet Gynecol 1979;133:292–294
3. Chin Y, Stanton S: A follow up of Silastic sling for genuine stress incontinence. Br J Obstet Gynaecol 1995;102:143–147
4. Nichols D: The Mersilene mesh gauze-hammock for severe urinary stress incontinence. Obstet Gynecol 1973;41:88–93
5. Cato R, Murray A: Teflon tape suspension for the control of stress incontinence. Br J Obstet Gynaecol 1981;53:364–367
6. Bent A, Ostergard D, Zaffuto-Zwick M: Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study. Am J Obstet Gynecol 1993;169: 198–204
7. Raz S: Modified bladder neck suspension for female stress incontinence. Urology 1981;17:82–85
8. Radomski S, Herschorn S: Laparoscopic Burch bladder neck suspension: early results. J Urol 1996;155:515–518

Address reprint requests to:
David R. Staskin, M.D.
Division of Urology
Beth Israel Hospital
330 Brookline Ave.
Boston, MA 02215